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**THE NAS GUARDIANS' CONSOLIDATED MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION**

I. THE NEED TO CERTIFY A CLASS OF GUARDIANS IS URGENT

The NAS¹ Children are the most vulnerable and blameless victims of the opioid crisis. Through no fault of their own, they were bathed in opioids while their nervous systems, organ systems, and bodies were forming *in utero*. At birth the symptoms of their opioid exposure were so great that they were diagnosed with NAS. Their sad plight does not end at diagnosis. Instead, they entered the world facing a host of additional and significant needs, challenges, and additional risks as a result of their NAS. Medical and scientific evidence makes clear that early monitoring and surveillance will benefit them. Yet, despite over two decades of an opioid crisis and hundreds of thousands of NAS births, there exists at no level, whether federal, state or local, a long-term (longitudinal), large scale medical surveillance of these children.

The Guardians of the NAS Children, are the only entities legally bound to provide the ongoing care the Children require, including the monitoring and surveillance necessary to address and understand the effects of their NAS. **These needs are urgent.** Plaintiffs' Expert Kanwaljeet "Sunny" Anand, Professor at Stanford Medical School,² writes:

[The] long-term impact [of the Opioids Crisis] is inestimable because of the pervasive and persistent effects of prenatal opioids on all aspects of an individual's development. Their cumulative burden of suffering, and the total impact of their exposures on all facets of our society is so huge and unparalleled in human history

¹ The children made the subject of these complaints were diagnosed at birth with Neonatal Abstinence Syndrome (NAS), also sometimes referred to as Neonatal Opioid Withdrawal Syndrome (NOWS), arising out of their birth mothers use of opioids during pregnancy.

² Dr. Anand, M.B.B.S., D.Phil, FAACP, FCCM, FRCPCH, is a Professor of Pediatrics, Anesthesiology, Perioperative & Pain Management at Stanford University School of Medicine. Dr. Anand graduated from M.G.M. Medical College in India, where he was awarded an M.B.B.S. As a Rhodes Scholar at the University of Oxford, UK, he received a Doctor of Philosophy, followed by a post-doctoral fellowship at Harvard Medical School, a categorical Pediatrics residency training at Boston Children's Hospital, and a Critical Care Medicine fellowship at Massachusetts General Hospital. Attached as Exhibit 5 to the Declaration of Marc Dann ("Dann Decl.") is the curriculum vitae and report of Dr. Anand.

that this is truly the real emergency. **Unless they are monitored-supported/treated NOW, the problems of these children will become intractable and unmanageable as they grow into adulthood, wiping away generations of human endeavor because of our short-sightedness.**

Anand Report, Dann Decl., Exhibit 5, at ¶ 2 (emphasis added).

Only the Guardians, who include grandparents, widowed single parents, adoptive parents, and other family members, are obligated to advance the best interest of the NAS Children. Only they can assert a current, justiciable claim against Defendants arising out of the NAS Children's special and ongoing medical needs and risks. Only they can secure relief that will **necessarily** result in aid to the NAS Children.³ Absent action by this Court on behalf of the Guardians and the NAS Children in their care, future courts will necessarily confront the "wreckage of the broken man" and know the sad futility of trying to value that wreckage in dollars. **This generation of children is not yet lost, but without intervention by this Court, they will be.**

It is our position that the critical needs of the NAS Children should not be subordinated to the less urgent desires of the cities and counties that have dominated this MDL. These cities and counties (1) do not have the legal ability to bring claims for the benefit of the NAS Children, (2) do not owe a duty of care to the NAS Children, and (3) will never guarantee that they will provide ongoing care for the benefit of the NAS Children. Contrast this with the Guardians who have a fiduciary obligation to advance the singular goal of immediate aid to the Children in their care.

Dr. Anand warns against their failure:

Such bleak outcomes portend a future tsunami of neurocognitive and neuro-psychiatric disorders among the children and youth with NAS. The Opioid Crisis has increased over the past 20 years; therefore, multiple generations of such

³ Without a nationwide certified class of Guardians focused on these needs alone, the creation of a medical monitoring program by some governmental entity is, at best, certain to be delayed for years. At worst, a medical monitoring program will never exist because (1) there is no guarantee that the patchwork of state and local government will commit funds to long-term programs, (2) these disparate entities lack the geographic jurisdiction to collect data from an equally disparate cohort of NAS children, and (3) there is no system of intergovernmental coordination that would otherwise allow them to tackle a national problem.

children and youth have been affected. While we continue to argue about priorities and preferences, these children are growing up – and every day that passes without the medical monitoring or supportive services being offered to these children, it makes their problems more and more intractable, imposing on them poorer outcomes and greater societal disadvantages.

Anand Report, Dann Decl., Exhibit 5, p. 8 (emphasis in original).

The window of opportunity to provide salutary relief to the NAS Children is rapidly closing. No future court will be able to undo their injuries or offer a chance at mitigation if monitoring and surveillance is delayed. For them, it is now or never. Certification of a nationwide class of Guardians of NAS Children must occur in 2020. Medical monitoring claims exist as injunctive relief to ensure that money needed to pay for testing and epidemiology is actually spent for that purpose. Monitoring, surveillance, and epidemiology on a population basis, not on an individual basis, benefits everyone within the affected population benefits from the data generated by testing and participating members, all of whom are subject to the same protocol.

The Guardians also wish to highlight one of the most appalling misdeeds to have occurred during the Opioid Crisis — the flow of prescription opioids to pregnant women, especially those enrolled in Medicaid. With nationwide numbers of over 20% of Medicaid-enrolled mothers being prescribed opioids, some states—including Ohio—have been hit even harder with upwards of 30% of pregnant mothers receiving opioids.⁴ Thus, the numbers of NAS Children within the Medicaid system are startling.

⁴ Attached as Dann Decl., Exhibit 8 is Desai, R.J., “Increase in Prescription Opioid Use during Pregnancy among Medicaid-enrolled Women,” *Obstetrics and Gynecology*, 123(5), 997-1002 (2014).

II. THE CLASS CLAIMS AND CLASS DEFINITIONS

In hope of speeding relief to the NAS Children and mitigating the care burden for them, the Guardians ask the Court to certify two different nation-wide classes asserting RICO claims. One nationwide class will be composed of Guardians of NAS Children whose birth mothers were prescribed opioids at any time before the child's birth, and that other will be composed of NAS Children whose birth mothers were prescribed opioids during her pregnancy.

The Guardians also ask the Court to certify an Ohio state-wide class asserting those same RICO claims, plus state law claims for negligence, negligence per se, battery, and conspiracy and a California state-wide class asserting RICO claims and similar state law claims to those brought in Ohio.⁵ Across all four class actions, the operative facts, class definitions, class-wide proof, and requested relief are uniform.

The Guardians seek certification of these nationwide⁶ classes:

The Expansive Nationwide Class

Legal Guardians⁷ of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS⁸ at or near birth and whose birth

⁵ Attached as Appendix A is a Master Summary of Plaintiffs' class and subclass definitions, as well as the causes of action asserted by those classes and subclasses and the Defendants against whom the claims are asserted.

⁶ As stated, the Guardians have also pleaded statewide classes for Ohio and California, which are similarly defined. *See* Appendix A.

⁷ The term "Legal Guardians" is defined as "any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities. "Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

⁸ The term "NAS" is defined "to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids."

Additional specifics on these readily identifiable and ascertainable terms are included in this Motion (and are based on the expert medical opinions of Dr. Anand), Dann Decl., Exhibit 5. "The Class Is Ascertainable and Based on Objective Criteria," *infra*, at VIII.A, which discusses the objective categories to be used for certification. The objective criteria will become part of both any order of certification and, eventually, class

mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

The Narrower Nationwide Class⁹

Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

Exclusions from All Classes (Including Statewide Classes)

Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of “custodian” of the child.

Alternative subclasses are:

- a. Legal Guardians¹⁰ of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the “Cephalon Defendants”;¹¹
- b. Legal Guardians¹² of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the “Endo Defendants”;¹³
- c. Legal Guardians¹⁴ of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates

notice and proof of claim.

⁹ The defined terms of “Legal Guardians” and “NAS” are the same for each class definition and are not repeated in this Memorandum again.

¹⁰ The term “Legal Guardian” is defined at fn. 1.

¹¹ Defined in the “Manufacturer Defendants” section, *supra*.

¹² The term “Legal Guardian” is defined at fn. 1.

¹³ Defined in the “Manufacturer Defendants” section, *supra*.

¹⁴ The term “Legal Guardian” is defined at fn. 1.

- were manufactured or distributed by one or more of the “Mallinckrodt Defendants”;¹⁵
- d. Legal Guardians¹⁶ of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the “Actavis Defendants”;¹⁷
 - e. Legal Guardians¹⁸ of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the “Janssen Defendants”;¹⁹
 - f. Legal Guardians²⁰ of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more Defendant or Purdue entity.²¹

In each class and subclass definition, the two primary objective and readily ascertainable criteria are obvious: (1) the birth mother of every NAS Child received a prescription for opioids prior to the birth of her child and (2) that child was medically diagnosed with NAS. By crafting the definitions in this manner, Guardians have excluded exposure-only victims who did not present with NAS symptoms at birth and receive a diagnosis of NAS. The weight of medical opinion is that when a child has been diagnosed with NAS, he or she absolutely requires medically-necessary

¹⁵ Defined in the “Manufacturer Defendants” section, *supra*.

¹⁶ The term “Legal Guardian” is defined at fn. 1.

¹⁷ Defined in the “Manufacturer Defendants” section, *supra*.

¹⁸ The term “Legal Guardian” is defined at fn. 1.

¹⁹ Defined in the “Manufacturer Defendants” section, *supra*.

²⁰ The term “Legal Guardian” is defined at fn. 1.

²¹ Defined in the “Non-Defendant, Co-Conspirator Purdue Entities” and “Defendant Co-Conspirator Purdue Entities” sections, *supra*.

surveillance and monitoring for both the existing effects of NAS, as well as the heightened risk of additional disease and disorders that may manifest in the future as a result of NAS.

It is also notable under these definitions and because of the nature of Defendants' alleged underlying conspiracy, that the birth mother's history of drug usage (other than the prescribed opioid required by the definition) is irrelevant. Whether the birth mother continued to draw down on a supply of opioids medically prescribed to her (including opioids-replacement therapy during pregnancy), whether she pivoted to the oversupplied diversionary market, or whether she even began her usage on that diversionary market before receiving a prescription for opioids does not matter. **But for the conspiracy to create the diversionary market and oversupply opioids to targeted, at-risk Americans who should not have access to addictive quantities or *not have access to opioids at all* (such as pregnant women, women of childbearing years, women co-using other addictive drugs, or women at risk for addiction), there would not exist two generations and hundreds of thousands of NAS Children in the United States.** And, yet, that is exactly what Defendants conspired to do, knowing full well the consequences of targeting at-risk Americans and at-risk communities. They cannot create the criminal conspiracy that resulted in this foreseeable and intended epidemic of addiction by birth mothers while also claiming that the individual mechanics of a birth mother's addiction protect them from the Guardians' claims arising out of their duty of care for the NAS Children.

III. THE GUARDIANS BEFORE THIS COURT

The following Guardians seek to be appointed as Class Representatives for the nationwide classes, and also as Class Representatives for the statewide classes of their respective states:

A. California and the Nation

1. Jacqueline and Roman Ramirez

Jacqueline and Roman Ramirez, California residents, are the birth parents and Guardians of Minor R.R., aged 14, the youngest of their three children and the only one born with NAS. R.R.'s parents have been married for over 30 years. Jacqueline was injured in 2001, while attending her older daughter's softball tournament. As a result of her injury, she was diagnosed with pain disorder and prescribed opioids. Jacqueline became dependent on opioids prior to becoming pregnant with R.R. She also continued to be prescribed opioids throughout her pregnancy. Minor R.R. was diagnosed at birth with NAS and discharged to the care of Jacqueline and Roman.

2. Melissa Barnwell

In 2004, Melissa Barnwell was severely injured when she was struck by a car. She had multiple broken bones and was prescribed opioids for chronic pain. During her pregnancy with minor C.G., Melissa's physicians continued to prescribe her opioids. Melissa is the birth mother of C.G., a 13-year-old minor child who resides in California with Melissa. C.G. was diagnosed at birth with NAS.

B. Ohio and the Nation

1. Michelle Frost

D.F. is a minor child residing in Ohio. He is two years old and lives with Michelle Frost, his legal guardian and biological grandmother. Ms. Frost became D.F.'s guardian in 2018. D.F.'s birth mother was prescribed opioids for pain treatment associated with a melanoma in her right eye which ultimately caused her eye to be removed. She subsequently became addicted, and, as a result, she was on Medication Assisted Therapy while pregnant with D.F. At birth D.F. was diagnosed with NAS. Not long after D.F.'s birth, his grandmother took over his care and later became his guardian.

2. Stephanie Howell

C.L. is a minor child who resides in Ohio with his biological mother and legal guardian Stephanie Howell. C.L. is currently five years old. He is the youngest of three children born to Stephanie, and her only child with NAS. In 2010, Stephanie was prescribed opioids for back pain, and she subsequently became addicted. She continued to be prescribed and take prescription opioids while she was pregnant with C.L.

IV. CLASS COUNSEL

The Putative Class Representatives have retained and employed for over the past two years a cohesive and well-functioning group of 20+ law firms to represent the interests of all Guardians and the NAS Children in this MDL and in other related actions. Of those firms, four have been selected by the Class Representatives to seek appointment as Class Counsel for the Guardian Classes. Attached and incorporated at Dann Decl., Exhibits 1, 2, 3, and 4, are the Declarations and Firm Resumes of these firms. These firms have a thorough understanding of the facts, relevant documents and claims asserted in this litigation. They also are highly experienced in class actions of this nature and have been appointed as Lead and Co-Lead Counsel in a number of complex class actions. They will fairly and adequately represent the interests of the Class.

A. Dann Law (Class Counsel and Liaison Counsel)

Marc Dann has practiced law for 33 years and has represented thousands of consumers individual and class action cases. Dann has served as Lead and Liaison counsel in the Sonic MDL and has been appointed class counsel in Miller v. Intellos and Lieber v. Wells Fargo in the Northern District of Ohio. Dann was elected Ohio Attorney General in 2006 and oversaw several MDL and class action matters where the State of Ohio served as lead counsel. Dann also served on the National Association of Attorneys General Committee overseeing the National Tobacco

Settlement. Dann and his firm have the financial resources to represent the interests of the Guardians of NAS Children before this court.

B. Martzell, Bickford & Centola (Class Counsel)

Scott R. Bickford of Martzell, Bickford & Centola of New Orleans, Louisiana, has practiced law for 36 years and has represented thousands of personal injury victims in class action, MDL and mass tort litigation. Bickford has been lead counsel in multiple civil and criminal trials including lead counsel in an MDL bellwether proceeding. Bickford is also an associate professor of law at Tulane Law School. Bickford and his firm have the financial resources to represent the interests of the Guardians of the NAS Children before this Court.

C. The Bilek Law Firm

Thomas E. Bilek of The Bilek Law Firm, L.L.P. of Houston, Texas (“Bilek Law”), has been appointed by courts as lead, co-lead, or liaison class counsel in over 20 certified class actions in state and federal courts. Bilek has practiced law for 33 years and specializes in mass and class actions arising from toxic exposures, environmental contamination, and securities fraud. Bilek is also one of the only attorneys in the United States to have tried two class actions to verdict as lead attorney. Bilek was co-liaison counsel in the class action *In re Enron Corp. Securities* that ultimately settled for \$7.2B. Bilek Law also was a committee chair in the class action *In re Deepwater Horizon*, which settled for in excess of \$10B. Bilek and his firm have the financial resources to represent the interests of the Guardians of the NAS Children before this Court.

D. The Cooper Law Firm

The Cooper Law Firm is a New Orleans based mass tort/class action firm specializing in representing plaintiffs. Cooper’s cases are large matters involving radiation exposure, toxic chemical exposure, and injuries arising from defective medical devices and pharmaceuticals. The firm has the resources to equip our class action team as it has done since this litigation was

originally instituted. Of counsel to the Cooper Law Firm is Stuart H. Smith a pioneer in the NORM litigation leading Smith to represent over 100 cancer victims harmed by radiation exposure. Smith was lead counsel in the landmark case of Grefer v. Alpha where he obtained a judgment of over one billion dollars against Exxon Mobil. Smith represented 1000s of plaintiffs- both individuals and businesses- in the BP oil spill. Celeste Brustowicz is the managing partner of the Cooper Law Firm. Celeste has practiced law for 34 years, primarily in Louisiana, but also in California (2007) and Mississippi (2011) where she is also licensed. Brustowicz obtained a B.A. in Political Science from Louisiana State University and a J.D. in 1985 from the Paul M. Hebert Law School at LSU. For over a decade, Brustowicz graded the torts portion of the Louisiana Bar examination. Brustowicz has been involved with many class actions over the years, representing states, counties, police agencies, and even judges in a variety of case types including civil rights, pharmaceutical, and torts matters.

V. BY CERTIFYING A CLASS OF GUARDIANS, THE COURT WILL ADVANCE THE GOALS OF THIS MDL

Certification of a class of Guardians will advance the MDL process in two important ways. First, it will put the Guardians and Class Counsel in the best position to negotiate a comprehensive resolution of the Guardians' and NAS Children's claims. Class Counsel already represents hundreds of NAS Children and Guardians individually and is in the process of building a larger group by working with lawyers who represent others individually. Certification of a class of Guardians will therefore facilitate negotiations with the potential to resolve all pending lawsuits in which NAS Children or their Guardians seek damages or injunctive relief.

Negotiations led by the PSC cannot resolve these cases. Although the cities and counties can release their own claims, they cannot release claims held individually by the Guardians or their wards. The *parens patriae* power does not extend that far. See X.E.1, "The Entities Neither

Represent the NAS Children *Parens Patriae*, Nor Can Release Their Claims". Because, as the Court observed when certifying the Negotiation Class, "Defendants have insisted throughout on the need for a 'global settlement' ... that resolves most, if not all, lawsuits against them arising out of the opioid epidemic," *In re: National Prescription Opiate Litigation*, Case No. 1:17-MD-2804, (N.D. Ohio), 2019 WL 4307851, the PSC's inability to release claims held by the Guardians and the NAS Children may be a serious obstacle to any eventual global settlement.

Second, certification of these classes will allow a significant number of identical claims to proceed expeditiously and efficiently within the MDL process, create desirable incentives for negotiation or settlement with Defendants, and allow for ultimate trial of the Guardians' claims for injunctive relief. Lawsuits by individual Guardians pit people with limited resources against Big Pharma, whose wealth and political power are infinitely greater. Aggregation will level the playing field by outfitting all Guardians with representation by lawyers whose financial incentives are tied to the recovery for the entire group. Individual lawsuits would also be duplicative and wasteful. Finally, class certification will promote accuracy at the remedies stage by facilitating the use of statistics that are far more reliable when applied to all Guardians collectively than when applied to Guardians one by one.

In January 2018, the Court expressed the desire "to do something meaningful to abate this crisis...." (Dkt. 58, p. 5). The Court then observed that meaningful action would address the need for "new systems" and "treatment." *Id.* at 9. ***This Motion offers the best opportunity the Court will have to provide meaningful relief.*** The States are actively working to sideline, and even shut down, the cities and counties' efforts to assert their own public nuisance claims and settle with Defendants. It is fair to say that, regardless of how that intragovernmental squabble works out, this Court will never receive a guarantee of how settlement funds secured by the governmental

entities will be spent. All that can be known is that both sides want Defendants' money for themselves, that they cannot be required to use any of the money to help victims of the crisis, and that they have historically demonstrated an unwillingness to use received funds to benefit individual victims. Unless the Court certifies a class of Guardians, there is a real danger that, despite years of effort, this MDL will end without helping any victims at all.

VI. THE GUARDIANS ARE NOT ASSERTING PERSONAL INJURY CLAIMS

Because litigation classes containing personal injury claims are disfavored, it is important to understand at the outset that **the Guardians are not asserting personal injury claims in their amended complaints.** The Guardians are suing only in their capacity as caregivers for symptomatic NAS Children who require urgent and specialized medical monitoring as a result of both their NAS status at birth and the host of additional needs and risks that arise for an NAS Child after birth. Medical monitoring classes *are* certifiable, as shown further below. The Guardians are asking the Court to follow an existing path, not to blaze a new one, in helping them to carry their heavy burden to care for the NAS Children and expeditiously secure this much-needed injunctive and declaratory relief.

VII. SPECIALIZED MEDICAL MONITORING AND ASSESSMENT MUST BEGIN IMMEDIATELY

"Unless they are monitored-supported/treated NOW, the problems of these children will become intractable and unmanageable as they grow into adulthood, wiping away generations of human endeavor because of our short-sightedness." Anand Report, Dann Decl., Exhibit 5.

The exigent and medically-necessary monitoring and surveillance needs of the NAS Children are fully briefed in Plaintiffs' expert reports that are relied on in this Memorandum, and which are attached and incorporated at Dann Decl., Exhibits 5, 6, and 7. The host of problems

after birth²² that these children and their caregivers face are overwhelming and include delayed and impaired cognitive development and long-term behavioral problems. The resultant increased care burden faced by the NAS Guardians is nondelegable, immense, and cannot be met without the intervention of this Court and an order of declaratory and injunctive relief that requires financing by the Defendant responsible parties. Regarding the timing of these efforts, “the best possible outcomes can only be achieved with proper management of NAS before hospital discharge, couple with increased monitoring and surveillance, as well as active multi-disciplinary interventions that are initiated just after birth and continued for the child’s entire childhood and adolescence (up to 18 years of age).” Anand Report, Dann Decl., Exhibit 5, at ¶ 4.

Plaintiffs are not, of course, required to prove the merits of their claims or requested relief at this stage, nor even establish a probability that they will be successful. *Eisen v. Carlisle & Jacqueline*, 417 U.S. 156, 177-78 (1974). Plaintiffs do, however, meet their obligation to provide “some” evidence favoring the underlying class claims for relief. *Wal-Mart Stores v. Dukes*, 564 U.S. 338, 350-51 (2011).

A. The Mechanism of Injury and Disease in Cases of NAS

Dr. Anand details extensively the mechanism of opioid exposure on brain development and brain growth.

Brain Development: Opioids have drastic and sustained effects on brain development in the fetal and postnatal periods, affecting the brain’s size, architecture, networks and connections between brain cells, neurochemical and other functions of each cell, as well as the brain DNA’s structure, its expression and regulation. Thus, prenatal opioid exposures have robust and long-term effects on the cognitive and behavioral outcomes of the individuals diagnosed with NAS. Opioids affect brain development by disrupting oligodendrocyte development,

²² At birth some of the NAS Children are also diagnosed with birth defects, including facial/oral defects, limb deformities, congenital neurological defects, and congenital heart defects. Anand Report, Dann Decl., Exhibit 5, *passim*. Other NAS Children, however, had such defects at birth, but they have not yet been diagnosed. The Surveillance Protocol provides for testing to identify such yet-undiagnosed defects. *Id.* at 9-11.

altering the temporal sequencing and quality of nerve fiber myelination, decreasing the growth of nerve cell dendrites, and their branching pattern complexity of pyramidal neurons in the cerebral cortex, and by suppressing cell proliferation and neuronal migration to the cortical plate. These effects may reduce regional brain volumes in the basal ganglia and other brain areas with lower developmental potential.

Brain Growth: A large number of studies have reported lower birth weights and smaller head circumferences in opioid-exposed babies with relatively increased risks in those exposed. A controlled comparison showed that reduced fetal head and body growth in infants of opioid-dependent mothers were not explained by gestational age, cigarette smoking, area deprivation, infant gender, maternal age or parity. Given the limited maternal/environmental effects on head circumference, it is likely that the robust effects of opioid exposure on head circumference occur by reducing brain growth. This was confirmed in a pilot study of 16 infants, where volumetric MRI scans showed smaller whole brain volumes and basal ganglia volumes compared to age-matched population means. In another follow-up MRI study that included 38 youths in the opioid-exposed group and 44 youths in the non-exposed group (aged 17 to 22 years), the drug-exposed group displayed smaller brain volumes, smaller surface areas of the cerebral cortex, and thinner cortical mantles than unexposed youth.

Anand Report, Dann Decl., Exhibit 5, at 5 (footnotes omitted).

As a result of the mechanisms of disease and injury discussed above, the increased care burden faced by the NAS Guardians is nondelegable, immense, and cannot be met without the intervention of this Court and an order of declaratory and injunctive relief that requires financing by the Defendant responsible parties. Regarding the timing of these efforts, “the best possible outcomes can only be achieved with proper management of NAS before hospital discharge, coupled with increased monitoring and surveillance, **as well as active multi-disciplinary interventions that are initiated just after birth and will continue for the child’s entire childhood and adolescence (up to 18 years of age). ”** Anand Report, Dann Decl., Exhibit 5, at ¶ 4 (emphasis added).

B. The Increased Risk of Additional and Future Disease and Disorder as a Result of NAS at Birth

That the care needs of diagnosed NAS child are both exigent and significant is addressed by Anand in his discussion of the long-term risks and consequences of this exposure.

Neurodevelopmental Consequences: Differences in neurodevelopment between children with and without exposure to prenatal opioids are related to the age at which they were assessed, with milder differences occurring at birth, greater differences during infancy and early childhood but widening gaps noted during school age and adolescence. Individuals with NAS at birth had impaired behavioral regulation, greater excitability and arousal, and poorer quality of their movements. Among infants and toddlers, NAS was associated with impaired mental and language development as well as poorer neuromotor and psychomotor development before 24 months of age. Because of the very limited roles for cognitive or executive functions in early childhood, studies performed in the younger age groups showed minimal differences in cognitive or executive functions with and without NAS (e.g., every infant is likely to fail an algebra test). In contrast, the Bayley Scales of Infant Development revealed more prominent neurodevelopment deficits, with greater vulnerability among boys than in girls. Assessment in later childhood revealed differences in IQ, motor performance, language performance, lower IQ scores, behavior and attention problems compared with unexposed children at 8.5 years of age. Children exposed to methadone prenatally also had elevated levels of aggression, fear, and anxiety. Even after controlling for their sociodemographic factors and birth mother's medical history, elevated symptoms of ADHD occurred in children who were exposed to prenatal opioids compared with children not exposed to opioids *in utero*.

Executive Functions: Executive functions are thinking skills that help us with the information processing, reasoning, planning, problem-solving, for coping with stress, regulating our emotions and managing our lives. As a child progresses through school, the executive functions assume greater importance in their academic success, goal setting, and employability. Children exposed to prenatal opioids have difficulties with information processing, poorer performance on a vigilance task, lower overall executive functioning¹⁰⁵, significantly lower visual acuity, impaired visual-motor and perceptual performances, and fewer goal-directed eye movements. Children with NAS were far more likely to have developmental delays and lower IQ, 2.3 times more likely to be hospitalized for neuropsychiatric disorders, 4.5 times more likely to be hospitalized for child abuse¹⁴⁴ and die during hospitalization, perform poorly on educational testing, and show cognitive disabilities requiring extra classroom therapies and services. CDC compared 1815 children with NAS and 5441 children without NAS (age 3-8 years). Children with NAS were more likely referred for disability evaluation (19.3% vs. 13.7%), have a learning disability (15.6% vs. 11.7%) and require classroom therapies (15.3% vs. 11.4%). These differences remained significant even after controlling for maternal smoking, maternal education, birth weight, gestational age, and/or NICU admission¹⁴⁶. Children with NAS had lower scores on standardized testing in grade 3; by grade 7, children with NAS were scoring lower than other children in grade 5 and showing progressively greater deficits¹⁴⁵. The increasingly

complex cognitive processing and executive functioning required within a competitive high school environment place these children with NAS at progressively greater disadvantage and much higher likelihood of adverse outcomes, thus widening the gap between those with and without NAS.

Neuropsychiatric outcomes: Although Uebel et al. (2015) had found that more children with NAS were hospitalized with neuropsychiatric disorders (adjustment, conduct, anxiety, emotional, or speech disorders), three recent studies have highlighted the very high prevalence and distribution of mental health conditions among individuals with prenatal opioids. Using a Medicaid database, Sherman et al. (2019) found that half of all children with NAS were diagnosed with mental disorder before age 5, compared with 30% of all other births. Children with NAS were more likely to have conduct disturbances (2.7-fold), hyperkinetic syndromes (2.6-fold), adjustment difficulties (2.5-fold), stress/anxiety disorders (1.5-fold), emotional problems (1.9-fold), childhood-onset psychoses (1.7-fold), intellectual disabilities (2.3-fold), specific developmental delays (1.7-fold). Mental health conditions were 1.6-fold more prevalent in children with a history of NAS than the opioid-exposed children without a history of NAS, and 1.4-fold higher among children with Medicaid vs. commercial health insurance (Table 2 from Conner et al., 2019). From a longitudinally followed youth cohort (17-22 years) with prenatal opioid exposures (\pm other drugs) who were adopted/fostered before 1 year of age, Nygaard et al. (2019) found **2- to 8-fold higher lifetime risk of mental disorders** compared to matched controls. These risks mainly included **major depression, alcohol abuse, ADHD, and aggressive behaviors** even after controlling for age, gender, and caregivers' education. These children not only engaged in sex at younger ages and had **more sexual partners** compared to controls, but also experienced **suicidality** (28.8%), **psychoses** (17.7%), or **antisocial personality disorder** (15.6%) more often than their peers.

Anand Report, Dann Decl, Exhibit 5, pp. 6-7 (internal footnotes omitted) (emphasis in original).

The enormity of the risks and challenges that the NAS Children face cannot be overstated. The Guardians need intervention from this Court to carry this immense care burden and that help must come swiftly.

C. The Medical Monitoring and Surveillance Program that Is Required

At the heart of the Guardians' claims is the imposition through injunctive and declaratory relief of a medical monitoring and assessment plan for the symptomatic NAS Children in their care. Attached at Anand Report, Dann Decl., Exhibit 5, pp. 9-12, is the "Protocol for Routine"²³

²³ The term "routine" is used by Dr. Anand to refer to the necessary monitoring and surveillance for all

Monitoring/Surveillance of Children Diagnosed with NAS at Birth” developed by Dr. Anand. For each critical developmental period in a child’s life,²⁴ Dr. Anand lays out the specific “Physical Health,” “Behavior/motor development,” “Cognition/learning,” “Mental Health,” and “Quality of Life” monitoring and surveillance care requirements for an NAS Child at each of those stages. A substantially similar protocol is set out by Dr. Carl Werntz²⁵ in his report, Dann Decl., Exhibit 6, “Proposed Medical Monitoring and Intervention Program,” at pp. 10-14, with categories of “Educational Component for Caretakers,” “Annual Assessment- Pediatrician,” “Educational Readiness Assessment,” “Additional (Specialist) Assessments,” “Additional/Social Risk Assessment,” and “Vocational Assessment and Recommendations.”

For example, at Years 03-05 under the Anand Protocol, a Guardian will need to discharge their unique and elevated care for an NAS Child in the area of “Cognition/Learning” by securing four different yearly tests—the Kaufman Assessment Battery for Children, Preschool Language Scale (PLS4), Behavior Rating of Executive Function- Preschool Version (BRIEF-P), and Conner’s Test—3rd edition (ADHD screen). *Id.* These are in addition to the yearly care requirement of twenty other tests and assessments for an NAS Child, and do not even include the general “Quality of Life” care burdens on a Guardian. *Id.*

Though there are minor variations across the case law of the fifty states regarding the availability of medical monitoring relief for asymptomatic claimants, these variations are irrelevant to the instant case which involves **symptomatic, NAS-diagnosed** children. Traditional

children diagnosed with NAS. To be clear, this protocol goes above, beyond, and is quite different from routine pediatric care of children not diagnosed with NAS or otherwise born addicted to opioids.

²⁴ Those periods are Year 01 (subdivided into 0-1 months, 1-6 months, 6-12 months), Year 02, Years 03-05, Years 06-09, Years 10-14, and Years 15-18. Anand Report, Dann Decl., Exhibit 5, at pp. 9-12.

²⁵ Dr. Werntz is a physician Board Certified in Preventative Medicine, specializing in Occupational and Environmental Medicine, with experience in developing and implementing medical monitoring and surveillance in both industrial and litigation contexts. Werntz Report, Dann Decl., Exhibit 6, *passim*.

legal debates about medical monitoring hinge on an exposed, but asymptomatic population, and have no applicability here.

The NAS Children for whom the Guardians have an absolute care duty are all symptomatic, having been diagnosed at birth with NAS. (To be clear, children who were exposed *in utero* to opioids but whose exposure did not result in a diagnosable case of NAS are excluded from the class definition.) Instead, these putative classes before the Court are defined to address the immediate needs of Guardians who do not have expert knowledge about the specific medical and developmental needs of the children they care for, nor the financial resources to carry such a heightened care burden.

Dr. Werntz writes:

The development of the human brain before and after birth is complex, and multifactorial. There are general themes about the timing of organ development, but the development of the pathways and mechanisms necessary for learning, understanding, decision making and behavior control are not completely understood. ... The long-term consequences of NAS for each child is multifactorial, depending on individual differences between humans that are difficult to determine with specificity but a medical monitoring program is necessary for all of NAS victims [because] they all face common risks of latent disease that can be mitigated and abated through medical monitoring.

Werntz Report, Dann Decl, Exhibit 6, at p. 5.

Plaintiff Guardians seek to transfer (or at least alleviate) their current heightened care burden for the symptomatic NAS Children (who are also at risk for additional latent diseases) onto the responsible parties. These underlying facts are not what is traditionally referred to in jurisprudence as “medical monitoring” which almost exclusively arise out of exposure-only underlying facts. Because these are not personal injury claims, but guardianship claims arising solely out of the care burden, the relief sought by the Guardians is roughly analogous to the judicially created construct of “medical monitoring,” but the causation leading to the necessity

relief in the instant case is entirely different. A review of the traditional legal framework for exposure-only, asymptomatic medical monitoring makes this distinction immediately obvious:

(1) Was there significant exposure? In this matter all exposures have, by definition, already reached the threshold of medical “significance” because they resulted in symptomatic NAS. To be clear, the class is defined to include only significant, symptomatic, and diagnosed disease and disorder.

(2) Was the substance to which the NAS Children were exposed toxic, hazardous, or otherwise has the potential risk for serious harm? Again, the class is defined to include only exposure to highly dangerous controlled substances that by definition have already resulted in significant, symptomatic, and diagnosed disease and disorder. Regardless, Plaintiffs’ experts address both the “toxicity” and the “seriousness of harm” in their reports.

(3) What is the relative increase in risk in those exposed? Once again, by definition the NAS Children already have significant, symptomatic, and diagnosed disease and disorder. Having already been diagnosed, they are also expected to have progression of symptoms as well as additional disease and symptoms that will manifest over childhood and adolescence that must be monitored for. There is no risk of developing NAS absent an exposure to opioids and there is no background level of opioids in the environment, nor other exposure routes for a fetus. Further, absent exposure to an opioid, there is no chance for the public at large to develop both addiction to that opioid, nor, when the exposure occurs *in utero*, to result in the significant additional risks of health and developmental problems beyond the initial NAS diagnosis. Plaintiffs’ expert reports detail the increased risk for all such known manifest and latent health problems of the NAS Children above and beyond that of an unexposed population that was not diagnosed at birth with NAS.

(4) Is monitoring for the effects of the disease medically reasonable and necessary?

Once opioid exposure reaches the level of significance such that a child has numerous manifest symptoms at birth and is diagnosed with NAS, the weight of medical opinion is that monitoring is medically reasonable and necessary. Again, by defining the class as only diagnosed cases, the medical reasonability and necessity is self-evident.

(5) Is the monitoring different from that normally recommended in the absence of exposure? Plaintiffs' experts have offered the Court a monitoring plan that is specifically tailored for both the needs and risks of symptomatic, diagnosed NAS Children that is different and beyond routine pediatric care.

(6) Is there clinical value in early detection and diagnosis? Because the care burden of all Guardians is to maximize health and developmental outcomes of the children in their care and protect them against negative outcomes, the value of early detection and diagnosis of health and developmental problems in children is also self-evident.

D. Convocation and Administration of a Science Panel

The Guardians have also requested the relief of the convocation of court-supervised²⁶ Science Panel(s), which shall collect and analyze medical monitoring results so that other heretofore unrecognized latent, dread diseases and symptoms that are associated with *in utero* exposure to opioids may be identified so that the Guardians may properly care for the NAS Children. The Science Panel will also allow medical professionals engaged in research and development of treatments and interventions for NAS Children to have access to a broader universe of data. The Guardians have requested a fund for expenses for maintenance and

²⁶ If a nationwide class is certified, then only one Science Panel need be convened. If, however, only statewide classes are certified then the originating courts have the discretion to coordinate with each other to on Science Panels.

administration of this Science Panel which shall be created by and costs borne by Defendants. The costs, nature, and extent of epidemiological studies and actions of the Science Panel(s) will be subject to approval and supervision of the courts pursuant to the Guardians and Counsel's recommendations and input. The Science Panel(s) will be composed of academic and medical institutions appointed by the courts in consultation with the Guardians and their Counsel.

Regarding the need for the Panel(s), the Guardians' experts write:

As mentioned several times, there is limited information on the long-term effects of NAS, and effectiveness of specific interventions. The final aspect of this [monitoring and surveillance] program would be a funded arrangement with an academic or public health organization to collect, curate, analyze and publish the results of the assessments, interventions, and outcomes of NAS survivors. This epidemiological component confers a medical benefit to the population.

Werntz Report, Dann Decl., Exhibit 6, "Data Collection, Analysis, and Publication," at p. 13.

It is certain that in the future new technology or better understandings of the long-term effects of NAS may require updating of this program. This could be based upon changes in medical knowledge, improvements in technology to detect diseases associated with these exposures, or additional conditions of concern that are identified by the epidemiologist. This protocol should be reviewed periodically by the supervising physician or a committee appointed for that purpose to ensure that the screenings and follow-up described herein remain consistent with best medical practice.

Id. at 14.

The establishment of Scientific Panels to participate in a medical monitoring program would, in my opinion, be beneficial for the following reasons. Monitoring for the post-natal consequences [of] NAS is reasonable and necessary, according to contemporary scientific principles. The monitoring program should include periodic diagnostic medical examinations, as there is clinical value in early detection and diagnosis.

Such Scientific Panels should be composed of experts from the multiple medical and scientific disciplines that are required to fully understand the complex condition, including (but not necessarily restricted to): paediatricians, epidemiologists, physicians specializing in opioid addiction, psychiatrists, behavioural psychologists, toxico-pathologists, [and] neurobiologists.

Howard Report²⁷, Dann Decl., Exhibit 7, at § 11, “Summary and Opinion.”

VIII. THE REQUIREMENTS FOR CLASS CERTIFICATION ARE MET

Certification of a class is proper when the requirements set out in Fed. R. Civ. P. 23(a) are met and the matter fits into at least one subpart of Rule 23(b). *See, e.g., Clemons v. Norton Healthcare Inc. Ret. Plan*, 890 F.3d 254, 278 (6th Cir. 2018). The requested NAS Guardianship Class satisfies all elements of Rule 23(a), as well as those in Rule 23(b)(2) and 23(b)(3).

A. The Class Is Ascertainable and Based on Objective Criteria

For a class action to be certified, the “class definition must be sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member of the proposed class.” *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 537-38 (6th Cir. 2012). *See also Cole v City of Memphis*, 839 F.3d 530, 541 (6th Cir. 2016). Administrative feasibility exists when membership can be determined on the basis of “objective criteria.” *Id.* at 538-39. *See also Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525 (6th Cir. 2015). “[P]erfection” is not the standard. *Young*, 693 F.3d at 537-38. As the Court noted when certifying the negotiation class, “minor technical issues can be worked out going forward.” 2019 WL 4307851.

Whether a class member meets the three objective criteria of the class definitions can be determined on the basis of documentary evidence, as explained in the subsections that follow. Class Counsel are ready, willing, and able to gather the documents that are required.

1. “Legal Guardian”

²⁷ Dr. Charles Vyvyan Howard is a toxico-pathologist specializing in the problems associated with the action of toxic substances on health, particularly during the period of development in the womb. He is an Emeritus Professor of Bioimaging at the University of Ulster and has authored/co-authored over 130 peer reviewed scientific papers, predominantly in the field of quantitative developmental toxicology. He is a Fellow of the Royal College of Pathologists, Fellow of the Collegium Ramazzini, Past President of the Royal Microscopical Society, Member of the British Society of Toxicopathologists, Past President of the International Society of Doctors for the Environment. Dann Decl, Exhibit 7.

The phrase “Legal Guardian” is further defined as “any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child’s physical, mental, and emotional development.” *See, e.g., Second Amended Class Action Complaint,* (“California Nationwide NAS Complaint”), (Dkt. 2747, n.155). (All class definitions are set out at Apx. A). It includes “natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.” *Id.*

Guardianship can be established simply and by reference to objective criteria. A person may document parenthood (natural or by adoption) by filing an affidavit along with a copy of a child’s birth certificate or adoption papers. A person may also establish all other forms of guardianship by filing a birth certificate and a copy of a judicial order of appointment.

Legal guardianship responsibility “under state law” does not, however, require a fifty-states analysis of the underlying guardianship laws, however. Whether someone has or has not been appointed as a guardian requires no legal analysis. It is a fact question: is there an order of appointment? Similarly, whether someone is an adoptive parent involves a question of legal status, not legal analysis. Is there an order of adoption?

2. “Medically Diagnosed with NAS”

In addition to Neonatal Abstinence Syndrome, the term NAS has been defined to encompasses “additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids.” Appendix A, *passim*. In addition to some states that have birth registries for children born with NAS, the objective medical criteria for such medical diagnosis can also be found in the child’s

medical records at birth.²⁸

Dr. Anand identifies those criteria as: (1) diagnosis of NAS or NOWS as documented in the child's medical record; (2) monitoring of NAS/NOWS score(s) after birth, meeting the diagnostic criteria he sets out; (3) postnatal weaning of the child with opioid replacement drugs (morphine, methadone, buprenorphine, or other opioids); and (4) opioid-positive toxicology screening of either umbilical cord blood or the baby's meconium.²⁹ Anand Report, Dann Decl., Exhibit 5, at "Definitions," ¶ 2 at p. 2.

3. The Birth Mother Received a Prescription for Opioids

Finally, in order to establish class membership after a settlement has been reached or a verdict secured, a Guardian must show that the NAS Child's mother received a prescription for opioids or opiates before the child was born. (Some Guardians will be able to provide prescriptions

²⁸ The Putative Class Representatives and Class Counsel are well-versed in the significant privacy and confidentiality issues relating both to minor children and to their medical records and how this will affect contemplated Notice in the Class.

Once the Court makes a decision about the type of classes, claims, and requested relief it wishes to certify, Class Counsel will craft Class Notice for its review (until such guidance is received, a nearly infinite number of Notices could result). Notice will include the following: (1) a description of the certified claims, parties, and requested relief; (2) a clear statement about what claims, i.e. personal injury, are not made the subject of the lawsuit and are not being certified and which must be brought, if at all, on an individual basis and within any applicable limitations periods; (3) a description of all confidentiality efforts that will be exercised by Class Counsel and the Claims Administrator to insure that minor identities and medical records will be protected and de-identified, as necessary; (4) a description of the three subjective criteria needed to establish membership in the class and how that criteria will be provided in a confidential and secure manner; (5) assuming membership in the class is established, an overview of how the child could be enrolled in the monitoring and surveillance program and an overview of the type of relief that will be sought at trial; and (6) all other standard requirements for class notice.

²⁹ Dr. Anand is of the professional opinion that medical monitoring and surveillance should be afforded to an even greater cohort of children than those for whom the Guardians bring this case—children whose birth mothers were diagnosed with OUD, but who do not otherwise meet the other objective diagnostic criteria, due mainly to the aversion of OB/GYNs to diagnose a child with NAS at birth due to the concern that the child will be taken away from the birth mother. The Guardians and putative class counsel recognize and feel deeply for this group of children but have not posited how that criteria soundly meets the Rule 23(a) requirement of objectivity and ready identification as do the others. To that end, the Class definitions advanced by the Guardians require diagnostic criteria for the child, not the birth mother.

issued during the birth mother's pregnancy, for which a separate class is sought.) All classes and subclasses can be proven with pharmacy records. Because membership in the class can be determined on the basis of documentary evidence, the administrative feasibility of fixing a class member's status is clear. It is also contemplated that Court Order regarding production of documents by the Pharmacy Defendants will assist Class Members in establishing this criteria.

B. The Subclasses

The Guardians ask *strictly in the alternative* for certification of a series of subclasses to be employed by this Court in the event that it finds that further refinement of the proposed class definitions are necessary. The alternative subclasses require that the birth mother's prescription be for an opioid produced by a specific manufacturing defendant, regardless of when the prescription was written or filled. The Guardians believe that because of the nature of the alleged conspiracy amongst the Defendants that their more expansive class definitions satisfy all requirements of Rule 23(a) and 23(b), but offer these subclass definitions for use by the Court if it does not agree with Plaintiffs' interpretation of the legal requirements. To be clear, however, the Guardians contend that joint and several liability for the conspiracy renders these subclasses moot.

C. The Requirements of Rule 23(a) Are Met

Having previously certified a nationwide class of cities and counties for the purpose of attempting to negotiate a global resolution of their claims, the Court is thoroughly familiar with the requirements set out in Rule 23. Movants therefore discuss the legal requirements as briefly as possible here.

Movants also abbreviate this discussion by adopting all findings made in the Court's *Memorandum Opinion Certifying Negotiation Class* that apply to the requested class of Guardians. See 2019 WL 4307851. This is appropriate because the Guardians adopted the counties' RICO pleadings by reference. *See, e.g., Second Amended California Nationwide Complaint,* (Dkt. 2747)

(adopting the Summit County complaint). The Court’s prior analysis of RICO claims and issues raised by the negotiation class of counties applies with full force to this motion. *See* 2019 WL 4307851.

1. The Class Is Sufficiently Numerous

Fed. R. Civ. P. 23(a)(1) permits a class to be certified when claimants are so numerous as to render the joinder as parties impracticable. *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 722 F.3d 838, 852 (6th Cir. 2013). Courts typically find that this requirement is met when the number of claimants is greater than 40 and the claimants are unknown or widely dispersed.

Since 2000, the start date for the class, tens of thousands of infants have been born with NAS. As Dr. Anand writes: “Based on trend analyses for birth mothers suffering from OUD [first usage, so spell this out] in pregnancy, approximately 36,000 babies [were] likely to [have been] born with prenatal opioid exposures in 2018” alone. Anand Report, Dann Decl., Exhibit 5, “The Numbers of Babies Exposed to Prenatal Opioids Annually,” at p. 2. Dr. Anand also includes for the Court the well-known “National Inpatient Sample” derived from the Healthcare Cost and Utilization Project for 1999-2014, and further projects up-to-date numbers which have grown to “10.1 per 1,000 delivery hospitalizations.” *Id.* at pp. 3-4.

The guardians for these children must be approximately equal in number and must also be widely dispersed. The numerosity requirement is plainly met.

2. Common Issues Exist

In *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349-50, 131 S. Ct. 2541, 2550-51, 180 L.Ed.2d 374, 389-90 (2011), the Supreme Court clarified the commonality requirement, stating the plaintiffs’ claims “must depend upon a common contention … that it is capable of classwide

resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.”

When certifying the PEC’s negotiation class, the Court found that the commonality requirement is met, for two reasons. First, when the JPML transferred the pending cases to this forum, it determined that “[a]ll of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation....” 2019 WL 4307851. Second, “there is direct evidence of the commonality of the claims and issues in this matter given that the short-form complaint process enabled MDL plaintiffs to adopt these specific claims and issues, and many did so.” *Id.*

Movants’ cases were transferred to this MDL by the JPML. Movants have also used the short-form complaint process to adopt Summit County’s claims. Both justifications for finding commonality therefore apply equally well to Movants’ request to certify a class of Guardians.

Because the Guardians request injunctive relief, the remedy stage raises additional issues that are common to the class. At trial, common evidence will establish (1) the necessary medical monitoring and assessment protocol to be followed for the NAS Children due to the known risks associated with their medically diagnosed conditions; and (2) the convocation of and establishment of parameters of inquiry for a Science Panel which will gather and analyze the data arising from the monitoring and assessment of the NAS Children.

3. The Named Plaintiffs’ Claims Are Typical

Rule 23(a)(3) requires that “the claims or defenses of the representative parties [be] typical of the claims or defenses of the class.” Fed. R. Civ. P. 23(a)(3). “Typicality is met if the class members’ claims are ‘fairly encompassed by the named plaintiffs’ claims’” such that “by pursuing their own interests, the class representatives also advocate the interests of the class members.” *In re Whirlpool Corp.*, 722 F.3d at 852-53 (6th Cir. 2013) (quoting *Sprague v. Gen. Motors Corp.*,

133 F.3d 388, 399 (6th Cir. 1998)). “[T]he plaintiffs’ claims need not be identical to those of the class; typicality will be satisfied so long as the named representatives’ claims share the same essential characteristics as the claims of the class at large.” 1 Newberg on Class Actions § 3:29 (internal quotation marks and footnotes omitted).

The putative Class Representatives are all (1) legal guardians of (2) children diagnosed at or near birth with NAS. Based on these two factors alone, the NAS Guardians’ claims are typical of all NAS Guardian class members who owe care duties to the NAS Children. Those care duties must be put before the NAS Guardians’ own needs and interests and are different from and beyond those they would owe to an ordinary child who does not have the risks arising from an NAS diagnosis.

When certifying a negotiation class at the request of the PEC, the Court observed that the cities and counties serving as named plaintiffs were typical because all such governmental entities are:

generally interested in the same end: recouping money they have been forced to pay to address the opioid epidemic and ameliorating that epidemic. If the Class Representatives pursue their own interests identified in these complaints, they will necessarily be pursuing the interests of the absent class members. There is nothing unique about any of the proposed Class Representatives that would set them apart in meaningful ways from the absent class members

2019 WL 4307851. *Mutatis mutandis*, the relationship between Plaintiffs and other guardians is the same.

It does not matter that some guardians will benefit from injunctive relief more than others because their wards’ injuries and their own care responsibilities are more severe. As the Court noted when granting the PEC’s motion:

[The] typicality requirement met where class representative’s and “other class members’ claims arise from the same practice...[and] the same defect...and are based on the same legal theory. Typicality is satisfied despite the different factual circumstances regarding the manifestation of the [defect]....”

2019 WL 4307851 (quoting *Daffin v. Ford Motor Co.*, 458 F.3d 549, 553 (6th Cir. 2006)).

The typicality of the putative class representatives and their claims is also borne out by the testimony of their well-qualified and experienced experts who opine that a medically necessary and class-wide medical monitoring and assessment plan which is uniform for all children diagnosed with NAS must be provided through injunctive relief so that the NAS Guardians may carry out their specific care duties. And, of course, the Science Panel which arises out of this monitoring and assessment will function in a uniform (and typical) manner, provide a uniform (and typical) benefit and further facilitate (in a typical manner) the execution of the NAS Guardians' care duties.

While it goes beyond the scope of this Motion, the NAS Guardians are well-aware of the governmental entities' representations that these care duties have already been/are being addressed by Medicaid or private insurance. The NAS Guardians are not suing to implement injunctive relief for routine pediatric care. Instead, the NAS Guardians are suing in order to obtain something very different and absolutely necessary for the at-risk NAS Children — implementation of a medical monitoring and assessment protocol developed by experts in NAS and the unique care needs it presents. *See Anand Report*, Dann Decl., Exhibit 5, at pp. 9-12, and *Werntz Report*, Dann Decl., Exhibit 6, at pp. 10-14.

In suing to implement this relief, the Class Representatives "also advocate the interests of Class members," who will receive the identical relief. *See In re Whirlpool*, 722 F.3d at 852-53. Indeed, the relief will function only if all NAS Guardians are able to ensure the enrollment of a significant number of NAS Children in the monitoring and assessment protocols. A Science Panel convened to analyze the monitoring and surveillance data of the random smattering of NAS Guardians who might be able to prosecute to verdict and preserve on appeal individual relief in 5-

7 years would do absolutely nothing to advance the medical and scientific knowledge in this field, nor would it allow a Science Panel to address the needs of the NAS Guardian caregivers and the NAS Children as they arise during the work of the Panel. *See Anand Report, Dann Decl., Exhibit 5 and Werntz Report, Dann Decl., Exhibit 6, passim.* At best, a series of individual case studies written by Medicaid-reimbursed doctors and physicians assistants might be the sole result absent the requested relief, but more likely, little will occur to advance medical knowledge about the plight of the NAS Children.

4. The Class Representatives Will Adequately Represent the Class

Rule 23(a)(4) requires that “the representative parties will fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a)(4). The Court looks to two criteria in determining adequacy of representation: “1) the representative must have common interests with unnamed members of the class, and 2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel.” *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 543 (6th Cir. 2012) (quoting *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1083 (6th Cir. 1996)). In addition, the proposed class representatives should not have any conflicts of interest with the class that they seek to represent. *Amchem Prods. Inc. v. Windsor*, 521 U.S. 591, 625 (1997).

As borne out by the fact sheet and discovery responses of the putative class representatives which are a matter of record in this proceeding, the Guardians have established that (1) they are members of the class, i.e., they are the Guardians of NAS Children; (2) they have the same interests as the class members and no conflict otherwise, i.e., they are legally obligated to carry out the heightened care duties owed to NAS Children and carrying out those care duties does not conflict with, nor adversely affect the ability of any other class member to do the same; and (3) the injuries they suffered are the same as those of the class members, i.e., they have an increased duty of care because the child in their care was diagnosed with NAS and has specific increased medical risks

and needs. Record, *passim*. The class representatives have no conflicts with the class and otherwise satisfy all requirements of Rule 23(a)(4). Additionally, the Court should consider their efforts in advancing these claims and supervising the litigation.

All while bearing the significant burdens of caring for NAS Children, Roman and Jacqueline Ramirez, Melissa Barnwell, Michelle Frost, and Stephanie Howell have been active participants in the prosecution of these claims and have established through the discovery process that they meet all criteria set forth in the class definitions. Record, *passim*. *See also* Declaration of Marc E. Dann on Confidential Medical Information of Plaintiffs' Wards, Plaintiffs' Discovery Responses [under seal]. Specifically, they have conducted numerous interviews to inform Plaintiff's Counsel about their claims; provided comprehensive information about the birth mother's history of opioid exposure; assisted counsel in coordinating discovery, including answering and reviewing questions for fact sheets and interrogatories; and submitted documentation and signed HIPAA forms to help confirm custody and validate their claims. *Id.* Also, during the pendency of this Motion, it is expected that they will be presented for deposition.

5. Class Counsel Are Adequate

The adequacy requirement in Rule 23(a) extends to Class Counsel. Rule 23(g), which requires the appointment of class counsel, directs the Court to consider: "(i) the work counsel has done in identifying or investigating potential claims in the action; (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (iii) counsel's knowledge of the applicable law; and (iv) the resources that counsel will commit to representing the class." Fed. R. Civ. P. 23(g).

Attached and incorporated by reference is the Declaration of Marc Dann which addresses the various efforts of Class Counsel since inception of these cases, competency issues relating to class counsel, and also includes the CVs for the law firms applying to be appointed as Lead

Counsel for the class. *See* Dann Decl., Exhibits 1, 2, 3, and 4. All have been actively engaged for years now in efforts to investigate and advance the interests of the Guardians and the NAS Children they care for in this MDL, as well as other multiple fronts, including bankruptcy and state court proceedings. *Id.* These firms also have substantial prior class action experience and have been appointed Lead and/or Liaison Class Counsel by state and federal courts throughout the United States. *Id.* The firms have the committed legal resources and ability to serve fully the needs of the putative classes and have no conflicts with class members. *Id.* Finally, the firms have engaged Professor Charles Silver, an authority on procedural and ethical issues in aggregate litigation, to help with questions that arise in the course of litigation and settlement negotiations.

6. The Elements of Rule 23(b)(2) Are Met Because the Class Chiefly Seeks a Declaratory Judgment and Uniform Injunctive Relief

The Guardians ask the Court to certify nationwide classes for injunctive and declaratory relief under Rule 23(b)(2), and additionally for damages under Rule 23(b)(3). The *Manual for Complex Litigation* observes that “Rule 23(b)(2) generally applies when the relief sought is a court-supervised program for periodic medical examination and research to detect diseases attributable to the product in question.” That is the relief the Guardians seek. *Accord Wilson v. Brush Wellman*, 817 N.E.2d 59, 65 (Ohio 2004) (“Court supervision and participation in medical-monitoring cases is a logical and sound basis on which to determine whether the action is injunctive. It has the added advantage of being a bright-line test, which can be readily and consistently applied.”).

The requirements of predominance and superiority do not apply to Rule 23(b)(2). Instead:

The key to the (b)(2) class is “the indivisible nature of the injunctive or declaratory remedy warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.” In other words, Rule 23(b)(2) applies only when a single injunction or declaratory judgment would provide relief to each member of the class.

Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 360, 131 S. Ct. 2541, 2557, 180 L. Ed. 2d 374 (2011); see Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. Rev. 97, 132 (2009). In *Dukes*, the Supreme Court found that certification under Rule 23(b)(2) was improper because the class members' claims for monetary relief belonged, if anywhere, under Rule 23(b)(3).

Here, Plaintiffs seek injunctive relief in the form of a medical monitoring program funded by Defendants. In *Dukes*, the Supreme Court did not discuss this form of relief, but in the article upon which it heavily relied, Professor Nagareda did—and his observations weigh heavily in favor of certifying Rule 23(b)(2) classes in cases that seek this form of relief. He first addressed medical monitoring classes in the following passage:

In toxic tort and product liability litigation, a frequent battleground for class certification concerns class actions that seek the establishment of a court-supervised program to provide medical monitoring for all persons in the exposed group so as to facilitate early detection of disease and, in turn, to mitigate its ultimate severity. Battles over the certification of medical monitoring classes remain high pitched, but their nature is such as to reinforce the content of governing law as the centerpiece of the certification dispute. The crux of the dispute concerns not the use of epidemiological evidence as part of the class certification determination but, instead, *whether governing law authorizes medical monitoring as an injunction-like remedy for exposed persons*. Only when governing law does so will the fact of exposure, in itself, operate to make all exposed persons the victims of the same wrong.

Nagareda, 84 N.Y.U. L. Rev. at 119–20. The point is straightforward: By establishing that the governing law entitles the Guardians to a medical monitoring remedy, the Guardians will satisfy the requirement contained in Rule 23(b)(2).

Nagareda later confirmed that medical monitoring is an indivisible remedy, that is, a remedy of the type that is suitable for certification under Rule 23(b)(2).

The gap in time between exposure and disease manifestation creates a window during which the defendant may be enjoined to take action to mitigate the effects of the tortious exposure. The analogy here is to the familiar notion that a motorist who negligently runs over a pedestrian is under an affirmative obligation to mitigate

the resulting harm—say, to take the injured person to the hospital for proper treatment. [] The medical monitoring remedy operates injunctively to enforce this affirmative obligation on the defendant's part. When properly crafted, the remedy also operates injunctively vis-à-vis exposed persons, covering their medical expenses only as incurred via the court-supervised monitoring program rather than simply paying them damages to spend as they wish.

Id. at 173 n.77.

In support of the propriety of certifying medical monitoring classes under (b)(2), Nagareda cited the American Law Institutes' Principles of the Law of Aggregate Litigation, § 2.04 of which discusses medical monitoring. The final version of that document states that (b)(2) certification is proper when the following conditions are met.

- (1) The evidence to be offered in support of liability "consists of epidemiological or other aggregate proof applicable to all those exposed to the disputed toxic substance";
- (2) "[T]he connection between the elevated risk of future disease and exposure to the substance for which Defendant is legally responsible does not involve individualized inquiry into the circumstances of particular persons";
- (3) "[A]ll persons allege that, in light of such exposure, a reasonable physician would prescribe a medical-monitoring regime above and beyond the medical services that such a physician otherwise would recommend"; and
- (4) "[S]uch monitoring will be instrumental in guiding medical intervention to mitigate the effects of disease manifestation, should disease ultimately occur."

Principles of the Law of Aggregate Litigation § 2.04, Illus. 3 (2010). When the identified conditions are met and the substantive law makes medical monitoring available as a remedy:

[T]hen the court should find that the requested relief demands a form of performance other than the distribution of money. Medical monitoring with the capacity to guide medical intervention to mitigate the effects of disease differs from the distribution of money to compensate for past harm, because the basis for the

claimed program stems from a shared risk among similarly situated persons. [T]he court has discretion to characterize such a remedy as indivisible and, hence, capable of treatment on an aggregate basis. Such a characterization would operate irrespective of whether applicable substantive law treats medical monitoring as a legal or equitable remedy.

Id.

The four conditions listed in the principles read like a roadmap of the trial of this case. First, the evidence to be offered in support of liability and causation will be the same evidence used to establish that the Defendants committed the alleged RICO violations. The Court has already found that “[a]s applied to Plaintiffs’ allegations concerning the existence of two national enterprises that disseminated a set of standard falsehoods in marketing and distributing opioids, all of the elements except injuries are common, not individual.” 2019 WL 4307851. And with respect to causation, the Court wrote, “Whether there was [] third-party reliance is a question susceptible to class-wide proof” as well. *Id.* The Court found that questions relating to the Controlled Substances Act, namely, the nature of Defendants’ responsibilities under the Act and their alleged failure to carry out those responsibilities, “are ‘capable of resolution with generalized, class-wide proof’ and ‘need only be answered once because the answers apply in the same way’ across the Class.” *Id.* at *3 (quoting *Martin v. Behr, Dayton Thermal Prod. LLC*, 896 F.3d 405, 414 (6th Cir. 2018)).

Second, injury will be proven by “epidemiological [and] other aggregate proof” that exposure to opioids *in utero* causes NAS and results in additional and substantial risk of other diseases and disorders. Because all members of the class are guardians whose wards were diagnosed with NAS at or near the time of birth, no individualized proof of exposure or injury will be required. Aggregate proof will also establish the link between exposure to opioids and an elevated risk of additional complications and future health impairments.

Third, all class members allege that, because of the children's exposure to opioids, "a reasonable physician would prescribe a medical-monitoring regime above and beyond the medical services that such a physician otherwise would recommend," and this too will be established by expert testimony at the aggregate level. *See* Anand Report, Dann Decl., Exhibit 5, at pp. 9-11; Werntz Report, Dann Decl., Exhibit 6, at pp. 10-14. Finally, expert testimony will also show at the aggregate level that monitoring will be instrumental in guiding medical intervention to mitigate the effects of NAS.

7. The Single-State Class Actions Are Also Certifiable under Rule 23(b)(2)

The reasons set forth above also establish that the Ohio and California statewide class actions meet the requirements for certification under Rule 23(b)(2). Although the Guardians prefer the certification of a single nationwide RICO class, they urge the Court to certify the single-state classes too so that the 6th Circuit will have all options before it.

8. All Actions Are Also Certifiable under Rule 23(b)(3)

Because of the unique nature of the relief requested, certification is most appropriate under Rule 23(b)(2). However, the Guardians are aware that most courts consider analyze a motion under both Rules 23(b)(2) and (b)(3) standards in event that a reviewing court finds that one or the other is more appropriate. Additionally, requests for punitive damages are also certifiable under Rule 23(b)(3).

Certification under Rule 23(b)(3) is appropriate where (1) "the questions of law or fact common to class members predominate over any questions affecting only individual members," and (2) class resolution is "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3).

The Court certified the PEC's negotiation class under subparagraph (b)(3) of Rule 23. When doing so, it found that common questions of law and fact predominate and that a class action

would be a superior method of adjudication. 2019 WL 4307851. Because the Guardians have adopted the counties' pleadings, including the portion relating to the RICO conspiracy, these findings apply to the Guardian's request to certify a Rule 23(b)(3) class with equal force.

To be clear, if the cities and counties are able to assert classwide claims arising out of the opioid crisis in their communities, then the Guardians are able to assert classwide claims for the opioid crisis in their own homes. Because the Guardians seek to require Defendants to fund a medical monitoring program that satisfies their clear and absolute duty to care for the NAS Children, their claims are actually more suitable for classwide treatment under Rule 23(b)(3) than the claims of the cities and counties for unrestricted lump sums of cash that can be spent however they want.

9. Common Issues Predominate

The Court set out the law governing the predominance requirement in its opinion certifying the City and County Negotiation Class, writing that “[t]he predominance inquiry consists of two steps: “[a] court must first characterize the issues in the case as common or individual and then weigh which predominate.” Common questions are those where “the same evidence will suffice for each member to make a *prima facie* showing.” 2019 WL 4307851. Notably, Rule 23(b)(3) does not require a complete absence of individual issues. A case may be certified under Rule 23(b)(3) even if there are some individual causation or damage issues. *See Martin*, 896 F.3d at 405; *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988). When a uniform and pervasive pattern of conduct is alleged, there is predominance even if the common conduct caused varying harm to individual class members. *Martin*, 896 F.3d at 408. *Accord Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1045 (2016).

When the Court certified the Negotiation Class under Rule 23(b)(3), it found that common issues predominate over individual ones. The overarching prevalence of the RICO marketing and

CSA abrogation claims throughout the pleadings supported this conclusion. As the Court wrote, “the Opioids Litigation raises questions of law and fact with common answers, and it is the answers to these common questions that predominate in importance—that matter most—to the advancement and disposition of the Opioids litigation. These are the questions that have consumed most of the Courts’, the Special Masters’, and the parties’ attention[.]” *Memorandum of Law*, (Dkt. 1820-1, at pp. 74-75). The Court added later that, “here, the entire class makes the same core factual allegations and the same core legal claims against the defendants who operated nationwide. And most of the evidence to prove those claims is exactly the same for every plaintiff.” *Id.* at 80. These findings are even truer for the Guardians, all of whose claims are stated in a single nationwide pleading, as contrasted with the 1300+ pleadings that were surveyed for common questions raised by the members of the Negotiation Class.

10. Anticipated Claims of Individual Issues Will Not Disrupt the Predominance Balance

While it is possible that Defendants will not launch a “blame the mother” campaign to dispute predominance, that is unlikely. It is not inappropriate for this Court to consider now that the very “individual” issues that Defendants are expected to rely upon in their predominance opposition are all themselves foreclosed to Defendants. These issues actually “turn on the [defendants’] common course of conduct,” which satisfies the predominance requirement. *In re Hyundai and Kia Fuel Economy Litigation*, 926 F.3d 539, 563 (9th Cir. 2019). The Guardians’ pleadings are unique because through their carefully crafted class definition and liability theory they have: (1) established how Defendants’ vast conspiracy to create the secondary, diversionary market for opioids obviates the need for any individual Guardian to establish product identification (or the route of any opioid through the pharmaceutical supply chain) specific to an NAS Child; (2) obviated the need for any dose calculation, because the NAS diagnosis at birth itself is proof of

the sufficiency of dosage; (3) excluded other potential sources of exposure, intervening causes, or the relevancy of unique medical histories as the exposure occurred *in utero*; (4) plead a completely uniform actual injury and common medical concern which is based on a credible, non-conjectural risk to the NAS Children which in turn gives rise to immediate and necessary care duties of the NAS Guardians for the benefit of the NAS Children; and (5) established the traceability of Defendants' bad acts to the Plaintiffs' harm through the class definition requirement of an opioid prescription for the birth mother. Defendants' traditional bases for opposing class certification cannot stand and this Court should exercise its discretion to come to the aid of the NAS Guardians and the Children for whom they owe the ultimate duty of care.

A thorough discussion of any alleged individual issues that Defendants actually claim will be found in the Guardians' reply brief. The limited discussion herein is meant only to apprise the Court that the Guardians have contemplated these challenges and are well-ready to establish that they are meritless in these proceedings. The examples below anticipate these arguments, but show that each is truly a common issue arising out Defendants' vast conspiracy and ultimate liability:

Example 1

Alleged individual issue: the birth mother of an NAS Child bought additional, non-prescription opioids in the diversionary market

True common issues: (1) Defendants created the scourge of addiction by hiding the significant risk from their products; (2) Defendants created both a source of and demand for additional opioids in that diversionary market; and (3) the diversionary market could never have existed but for Defendant's conspiracy to violate the Controlled Substances Act

Example 2

Alleged individual issue: the birth mother of an NAS Child used other prescription or illegal drugs during her pregnancy

True common issues: (1) Defendants conspired to market drugs to women of child-bearing age and pregnant women regardless of the birth mother's previous or current drug usage and (2) Defendants conspired to mislead medical providers and the public about the highly addictive quality of those drugs as compared to their limited benefit, especially where the birth mother was already using other prescription or illegal drugs and/or had access to the illegal/diversionary market

Example 3

Alleged individual issue: the birth mother of an NAS Child had a drug addiction before she was prescribed opiates

True common issue: Defendants conspired to market drugs to women of child-bearing age and pregnant women without a determination of whether that woman already had a drug addiction or otherwise fit the profile for being at-risk of addiction

Thus, as this Court undertakes its predominance inquiry, it should be mindful that the anticipated “individual issues” that Defendants will likely raise are themselves part of the alleged bad acts and conspiracy that were intended by Defendants. Simply put, when Defendants conspire to addict and then illegally supply the addiction of an entire populace, they cannot avoid legal responsibility by claiming that their products were consumed by addicts who, shockingly, might have additionally supplied their addiction from that illegal, diversionary market. That would be a neat trick, but tortfeasors cannot use their greatest intentional misdeeds to shift blame onto the victims.

The predominance requirement is met in the requested nationwide and single-state class actions for the same reason. The evidence relating to the conspiracy, including documents and fact and expert testimony, will be the same for all Guardians on both the federal and state law claims. Because the remedy sought is a medical monitoring program, proof at the remedy stage will be common to all Guardians too.³⁰

11. A Class Action Is Superior to Other Ways of Proceeding

When certifying the Negotiation Class, the Court found that the superiority requirement was met because the four factors listed in Rule 23(b)(3)(A)–(D) “all cut in favor of certification of both the two RICO claims and two CSA issues as against all Defendants.” 2019 WL 4307851.

³⁰ Additional discussions of the certifiable quality of the statewide Ohio and California complaints and the state law claims alleged therein follow at the end of this consolidated memorandum.

The same holds true for the nationwide and single-state classes for which certification is requested by the Guardians.

a) The class members' interests in individually controlling the prosecution or defense of separate actions

As was true for the cities and counties, the Guardian class consists of thousands of persons, few of whom have been able to prosecute individual actions. Although the exact percentage of the Guardians who are actively litigating is not known, “[t]he vast bulk of class members are not actively involved in opioid litigation” and “[t]his factor cuts in favor of certifying a nationwide class.” *Id.*

As was also true for the negotiation class, any guardian who may be “interested in individually controlling its action can opt out and the proposed procedure will in no way interfere with that individual litigation.” Moreover, by communicating with class members via notice and the internet post-certification, Class Counsel can “engage[] absent class members” in the litigation and in any settlement negotiations that may occur. *Id.* By this means, absent Guardians can decide whether their interests and those of their wards are best served by remaining in or opting out of the class.

b) The extent and nature of any litigation concerning the controversy already begun by or against class members

There are more than a dozen individual and putative class action cases within this federal MDL and many more filed in state courts that relate to the NAS Children and their Guardians. Per order by this Court, only four putative classes may apply for class certification. Discovery relating these putative class representatives as well as their class experts has proceeded under the Court’s scheduling order. Other than these claims, all others are at earlier litigation phases. The proposed Guardians’ class will not displace nor interfere with any of this other litigation. At the same time, this other litigation will resolve only a small quantity of the putative class’s claims, and, indeed,

cannot result in the same valuable relief (especially as respects the convocation of a Science Panel) to all Guardian's and NAS Children than if individual relief was pursued. All of these factors weigh in favor of certifying a nationwide class which can deliver monitoring and surveillance relief to a large cohort of NAS Children (thereby alleviating their Guardians' care burden), and drive that data into a much-needed Science Panel.

c) The desirability or undesirability of concentrating the litigation of the claims in the particular forum

The JPML has already coordinated the many pending cases in this forum and the issue need not be revisited. This factor therefore supports certification of the class, as it is an efficient means of resolving the many cases pending now and the multitude of individual actions that will follow if certification is not granted.

d) The likely difficulties in managing a class action

Management of a nationwide class of Guardians who chiefly seek declaratory and injunctive relief which will allow the NAS Children in their care to receive necessary medical monitoring and surveillance will not be especially difficult. Trial of the common issues will resolve all matters that establish the necessity of the relief, the nature of the relief, and liability for providing the relief as a result of the conspiracy by Defendants. Notice to the Class will provide members with a thorough explanation of how to prove membership, and how to enroll the monitoring protocol once membership has been established.

IX. INJUNCTIVE RELIEF IS AVAILABLE UNDER RICO

As discussed *supra*, certification of an injunctive class is proper under Rule 23(b)(2) when the governing law entitles the claimants to this form of relief. Whether injunctive relief is an available remedy under RICO has been addressed by some federal circuits, but not by the Sixth Circuit. A review of the cases shows that the better view is that RICO makes available equitable

relief. In the event that this Court or a reviewing court does not agree, then the requested relief can be also be categorized (and has been alternatively plead) as monetary relief to be awarded in the form of a trust for the use and benefit of the Guardians to discharge their care duties to the NAS Children.

The Second Circuit has held that “RICO authorizes private rights of action for injunctive relief.” *Gingras v. Think Fin., Inc.*, 922 F.3d 112, 124 (2d Cir. 2019). *Compare Religious Tech. Ctr. v. Wollersheim*, 796 F.2d 1076 (9th Cir. 1986) (injunctive relief not available to private parties under RICO). The decisive case in the Second Circuit is *Chevron Corp. v. Donziger*, 833 F.3d 74, 137 (2d Cir. 2016), in which the Second Circuit read subsection (a) of § 1964 as expansively authorizing federal courts to exercise their traditional equity powers:

When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of the statutory purposes. As ... long ago recognized, “there is inherent in the Courts of Equity a jurisdiction to ... give effect to the policy of the legislature.”

Id. at 137 (quoting *United States v. Sasso*, 215 F.3d 283, 289 (2d Cir. 2000)). The Second Circuit then stated specifically that “§ 1964, subsection (a) gives the federal courts jurisdiction to hear RICO claims and sets out general remedies, including injunctive relief,” *id.* at 138, and added that its

interpretation of § 1964 as authorizing the grant of equitable relief to private plaintiffs is consistent with Congress’s intent “to ‘encourag[e] civil litigation to supplement Government efforts to deter and penalize the ... prohibited practices. The object of civil RICO is thus not merely to compensate victims but to turn them into prosecutors, “private attorneys general,” dedicated to eliminating racketeering activity.’” [*National Organization for Women, Inc. v. Scheidler*, 267 F.3d 687, 698 (7th Cir. 2001)] (quoting *Rotella v. Wood*, 528 U.S. 549, 557, 120 S.Ct. 1075, 145 L.Ed.2d 1047 (2000)); *cf. Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 492 n.10, 105 S.Ct. 3275, 87 L.Ed.2d 346 (1985) (“Indeed, if Congress’ liberal-construction mandate is to be applied anywhere, it is in § 1964, where RICO’s remedial purposes are most evident.”).

Id. at 139.

In the passage just quoted, the Second Circuit relied upon *National Organization for Women, Inc. v. Scheidler*, 267 F.3d 687 (7th Cir. 2001), in which the Seventh Circuit also ruled in favor of the availability of injunctive relief. Although *Scheidler* was reversed on other grounds, see *Scheidler v. NOW, Inc.*, 537 U.S. 393, 397, 123 S. Ct. 1057, 1061, 154 L.Ed.2d 991, 999 (2003), its discussion of the availability of equitable relief remains good law, and has been relied upon in other circuits. See *CGC Holding Co., LLC v. Hutchens*, No. 11-CV-01012-RBJ-KLM, 2017 WL 4621094, at *4 (D. Colo. Sept. 26, 2017) (unpublished) (holding that a “constructive trust in appropriate circumstances could promote the objectives of subsection [1964](a) because it limits the [RICO] violator’s ability to retain or conceal property traceable to monies extracted from the victim by fraud”); *Absolute Activist Value Master Fund Ltd. v. Devine*, No. 215CV328FTM29MRM, 2016 WL 1572388, at *4 (M.D. Fla. Apr. 19, 2016) (finding “the reasoning in *Scheidler* to be persuasive” and noting that “[o]ther courts have found that injunctive relief is available to private litigants in a civil federal RICO action”). See also *Bennett v. Berg*, 685 F.2d 1053, 1064-65 (8th Cir. 1982) (injunctive relief possibly available), aff’d on reh’g, 710 F.2d 1361 (8th Cir. 1983); *In re Managed Care Litig.*, 298 F. Supp. 2d 1259, 1282-83 (S.D. Fla. 2003) (finding that the civil remedies portion of the federal RICO act authorized injunctive and declaratory relief to private plaintiffs); and *Motorola Credit Corp. v. Uzan*, 202 F. Supp. 2d 239, 243-44 (S.D.N.Y. 2002) (finding that courts have inherent equitable powers to grant injunctive relief in civil cases, including civil RICO actions), remanded on other grounds, 322 F.3d 130 (2d Cir. 2003).

In the district court proceeding in *Donziger*, Judge Jed Rakoff explained why the Second Circuit decision in *Scheidler* got the law right.

The Supreme Court repeatedly has rejected efforts to curtail the scope of civil RICO actions where courts ignore Congress’s insistence that the statute be “liberally

construed to effectuate its remedial purposes.” Indeed, if Congress’ liberal-construction mandate is to be applied anywhere, it is in § 1964, where RICO’s remedial purposes are most evident.”

This reading is supported also by the context in which RICO was enacted, a context of which Congress is deemed to have been aware. Article III of the Constitution provides that the judicial power of the United States extends “to all Cases, in Law and Equity.” Congress implemented Article III in 1789 by conferring “jurisdiction over ‘all suits ... in equity.’” The Supreme Court has rejected efforts to curtail the equitable powers of district courts in cases in which they otherwise have subject matter jurisdiction unless “a statute in so many words, or by a necessary and inescapable inference, restricts the court’s jurisdiction in equity.

RICO does not “in so many words, or by a necessary and inescapable inference,” foreclose equitable relief in actions brought by private plaintiffs. Accordingly, this Court agrees with *Motorola Credit Corp. v. Uzan*, that “[i]t would be extraordinary indeed if Congress, in enacting a statute that Congress expressly specified was to be ‘liberally construed to effectuate its remedial purposes,’ intended, without expressly so stating, to deprive the district courts of utilizing this classic remedial power in private civil actions brought under the act. Absent just such an express Congressional deprivation, the Court declines to divest itself of equitable powers that the Framers intended district courts to have and that they have possessed since 1789.

Donziger, 974 F. Supp. 2d at 568–70.

X. ADDITIONAL LEGAL ANALYSIS OF THE STATEWIDE CLAIMS

A. The Ohio State Law Claims

In their Second Amended Complaint, Plaintiffs assert claims on behalf of the Ohio Guardians for Negligence (Third Cause of Action), Negligence Per Se (Fourth Cause of Action), Battery (Fifth Cause of Action), and Civil Conspiracy (Sixth Cause of Action). In addition, Plaintiffs seek equitable relief including ongoing medical monitoring, the creation of a Science Panel for epidemiological studies, and alternatively, recovery of compensatory damages. Plaintiffs also seek punitive damages. As shown below, these state law claims are appropriate for class certification.

As an initial matter, Ohio law clearly authorizes Legal Guardian plaintiffs, such as the Putative Class Representatives, to file suit on behalf of themselves solely in their capacity as legal

guardians for the NAS children. Ohio law imposes upon Legal Guardians the legal duty to protect the welfare of the NAS Children in their care. Ohio Admin. Code. § 3109.401 (“State Policy on Parent and Child Relationship) (“parents have the responsibility to make decisions and perform other parenting functions necessary for the care and growth of their children.”); Ohio Admin. Code § 5101-2-1 (171) and (206) (legal custodians have a duty to “provide” children with “medical care[.]”) Ohio law further imposes a duty upon parents and guardians to support minor children, including furnishing and paying for necessities including medical care. R.C. § 3103.03(A), (D); *see also Univ. of Cincinnati Hosp. v. Cohen*, First App. Dist., 57 Ohio App. 3d 30, 31 (“Since medical services constitute necessities, a parent having custody of a child is likewise liable for the debt under an implied contract for the minor child’s medical care because of the duty to support required by R.C. 3103.03.”). An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian’s unlimited, and non-delegable duty of care owed to the child, as well as the duty of care, custody, and control of the Legal Guardian over children in their custody.

Additionally, as each of the Defendants acted in concert (*see* Second Amended Complaint, ¶ 13), resulting in damage to the Plaintiffs and Putative Legal Guardian Class, each Defendant, as a participant in the wrongful acts is equally liable. *Williams v. Aetna Fin. Co.*, 83 Ohio St. 3d 464, 476 (1998) (“In a conspiracy, the acts of co-conspirators are attributable to each other.”); *Matthews v. New Century Mortgage Corp.*, 185 F. Supp. 2d 874, 889 (S.D. Ohio 2002) (holding that each conspirator in a civil conspiracy is equally liable for each other’s acts).

1. Negligence Claim (Third Cause of Action)

Under Ohio law, the elements of negligence are the existence of a duty of care, breach of that duty and proximate cause resulting in injury. *Menifee v. Ohio Welding Products*, 15 Ohio St. 3d 75, 77 (1984). Plaintiffs have alleged, *inter alia*, that each Defendant owed a duty to the Legal Guardians, and that duty fell below the reasonable standard of care and was negligent in numerous

ways. (See, e.g., Amended Complaint at ¶ 419.) Both of these elements present significant common issues of fact that can be determined on a class wide basis. See, e.g., *Barrow v. New Miami*, Ohio 12th Dist., 58 N.E. 3d 532, 542 (2016) (holding that common issues of fact exist where a claim has the potential to generate common answers that drive the resolution of the litigation, and class members share a common prayer for relief). The remaining element, proximate cause resulting in injury, is also a common issue of fact to Plaintiffs and all Class Members.

2. The Negligence Per Se Claim (Fourth Cause of Action)

Under Ohio law, “where a legislative enactment imposes a specific duty for the safety of others, failure to perform that duty is negligence *per se*.¹” *Chambers v. St. Mary’s School*, 82 Ohio St. 3d 563, 565 (1998). In their Fifth Cause of Action, Plaintiffs assert that Defendants have violated 21 U.S.C. § 823(a) and implementing regulations, the purpose of which is to, among other things, maintain effective controls against diversion of controlled substances such as opioids, and protect the health and general welfare of the American people. NAS children are within the class of persons for whose protection the statute and regulations were adopted. Defendants’ violations of these provisions have led to the injuries suffered by Legal Guardians and Putative Class Members. As with the elements of negligence, each element required for the negligence per se action presents a common issue of fact.

3. Battery (Fifth Cause of Action)

In their Fifth Cause of Action, Plaintiffs assert state tort claims for battery. Courts have long recognized an individual’s interest in the physical security of their person and the integrity of their body, and violation of this interest is actionable through the tort claim of battery. Unwanted or unconsented to touching of the body, including through the administration of drugs or treatment

by a physician in a non-emergency situation without first obtaining the individual's informed consent constitutes battery. *Davis v. Hubbard*, 506 F. Supp. 915, 930-33 (N.D. Ohio 1980).

Here, Plaintiffs have alleged injury to the Legal Guardians by Defendants' intentional and unconsented-to touching of the NAS Children by opiates manufactured and/or distributed by Defendants. The touching was both direct and entirely foreseeable because of the known health risks to birth mothers, the known risks of NAS to the infants they carried, and the known adverse impact and increased burden on the ability of the Legal Guardians to care for the NAS Children after birth. These claims are appropriate for class treatment because Plaintiffs' battery claim presents a common issue of fact.

4. Civil Conspiracy (Sixth Cause of Action)

Ohio law recognizes a cause of action for civil conspiracy, which is "a malicious combination of two or more persons to injure another in person or property, in a way not competent for one alone, resulting in actual damages." *Kenty v. Transamerica Premium Ins.*, 72 Ohio St. 3d 415, 419 (1995); *LeFort v. Century 21-Maitland Realty Co.*, 32 Ohio St. 3d 121, 126 (1987). A civil conspiracy requires an underlying unlawful act. *Gosden v. Louis*, 116 Ohio App.3d 195, 219 (1996). A "malicious combination" exists between defendants where there is a common understanding or design to commit an unlawful act, and there is no requirement of an express agreement or meeting among defendants. *Gosden v. Louis*, 9th Dist., 116 Ohio App.3d 195, 219 (1996).

When the mischief is accomplished, the conspiracy becomes important, as it affects that means and measure of redress; for the party wronged may look beyond the actual participants in committing the injury, and join with them as defendants all who conspired to accomplish it. The significance of the conspiracy consists, therefore, in this: That it gives the person injured a remedy against parties not otherwise connected with the wrong. It is also significant as constituting matter of aggravation, and as such tending to increase the plaintiff's recovery.

Minarik v. Nagy, Cuyahoga Court of Appeals, 8 Ohio App.2d 194, 195 (1963). These claims are appropriate for class treatment because Plaintiffs' civil conspiracy claim presents a common issue of fact.

5. Medical Monitoring

Court-supervised medical monitoring is recognized as an equitable remedy available under Ohio law when liability is established under traditional tort theories. *See, e.g., Hirsch v. CSX Transp. Inc.*, 656 F.3d 359, 363 (6th Cir. 2011); *Baker v. Chevron U.S.A. Inc.*, 533 Fed. App'x 509, 517 (6th Cir. 2013); *see also Wilson v. Brush Wellman*, 103 Ohio St.3d 538, 2004-Ohio-5847, 817 N.E.2d 59 (2004); *Hardwick v. 3M Co.*, Case No. 18-CV-1185, 2019 U.S. Dist. Lexis 169322, *6-9 (S.D. Ohio Sept. 30, 2019) (also discussing the relief of a court-supervised Science Panel). In order to be entitled to medical monitoring, a plaintiff must show exposure to an increased risk of disease that warrants medical monitoring by demonstrating that the expenses are reasonable and that a reasonable physician would order medical monitoring under the circumstances. *Hirsch*, 656 F.3d at 363. As to a Science Panel, the *Hardwick* court writes: “[R]equesting oversight of further scientific study in some fashion in an Ohio tort claim with medical monitoring as the remedy is not exceptional.” 2019 U.S. Dist. Lexis 169322, at 18. As shown by the Guardians’ experts, in order to safeguard the NAS children, Plaintiffs and each of the Putative Class Members must demand, among other things, ongoing medical testing and monitoring of NAS children, and the effect of those efforts must be amplified to further benefit the NAS Children by convening a Science Panel to study those results.

B. The California State Law Claims³¹

³¹ The California Guardians also assert federal RICO claims. The previous discussion of certification of these claims on a nationwide basis apply equally to a request for a certification of a California-only class and are incorporated by reference.

In their Second Amended Complaint, Plaintiffs assert state claims on behalf of the California Subclass for Negligence (Third Cause of Action), Negligence Per Se (Fourth Cause of Action) and Violations of the Unfair Competition Law (“UCL”) (Fifth Cause of Action). In addition to remedies outlined under the UCL, Plaintiffs seek, *inter alia*, equitable relief including ongoing medical monitoring, the creation of a Science Panel for epidemiological studies, and alternatively, recovery of compensatory damages. Plaintiffs also seek punitive damages. As shown below, these state claims are appropriate for class certification under Rule 23(b)(2).

As an initial matter, legal guardians in California, not only have the right, but have the responsibility to take care of the child’s medical needs, making sure he or she gets proper care.³² Indeed, Guardians have a fiduciary relationship to the wards. *See, e.g., Persson v. Smart Inventions, Inc.*, 125 Cal App 4th 1141, 1160 (2005); *Patriot Scientific Corp. v. Korodi*, 504 F. Supp. 2d 952, 966 (S.D. Cal. 2007). *See also* Cal. Fam. Code § 3900 (parents have duty to support child).

California courts have long allowed parents to sue for medical expenses that they incurred as a result of defendants’ wrongful actions. *See Laughner v. Byrne*, 18 Cal.App.4th 904, 909 (1993) (“When a parent brings the action, loss of services, medical attention, expenses of nursing, and the like are compensable to parents. (*McManus v. Arnold Taxi Corp.* (1927) 82 Cal.App. 215, 255 P. 755.”); *Valenzuela v. Millard*, 2002 WL 31658571 (Cal.App. 3d, November 26, 2002) (authorizing parents to pursue independent action for incurred expenses for medical care, services and supplies for the treatment of their minor child). The Legal Guardians clearly have authority to seek relief in this action which seeks the exact same effect of meeting their legal care burden for the NAS Children.

³² Attached as Dann Decl., Exhibit 10 is California Courts, Duties of a Guardian (<https://www.courts.ca.gov/1211.htm>).

Additionally, as each Defendant acted in concert (*see, e.g.*, Second Amended Complaint, ¶ 13), which conduct resulted in damage to the Plaintiffs and Putative Legal Guardian Class, each Defendant, as a participant in the wrongful acts is “responsible as a joint tortfeasor for all damages ensuing from the wrong, irrespective of whether or not he was a direct actor and regardless of the degree of the activity.” *Applied Equipment Corp. v. Litton Saudi Arabia, Ltd.*, 7 Cal.4th 503, 511 (Cal.1994).

1. The Negligence Claim (Third Cause of Action)

Under California law, the elements of negligence are the existence of a duty of care, breach of that duty and proximate cause resulting in injury. *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 477 (2001). Plaintiffs have alleged, *inter alia*, that each of the Defendants owed a duty to the Legal Guardians, and that duty fell below the reasonable standard of care and was negligent in numerous ways. Both of these elements present significant common issues of fact that can be determined on a class-wide basis. *See Lockheed Martin v. Carillo*, 29 Cal. 4th 1096, 1107 (2003) (duty of polluters to class members and determination of whether defendant’s conduct was negligent are common issues of fact). The remaining element, proximate cause resulting in injury, is also a common issue of fact to Plaintiffs and all Class Members.

2. The Negligence Per Se Claim (Fourth Cause of Action)

Under California law, the elements of negligence per se are: “(1) the defendant violated a statute, ordinance, or regulation of a public entity; (2) the violation proximately caused death or injury to person or property; (3) the death or injury resulted from an occurrence the nature of which the statute, ordinance, or regulation was designed to prevent; and (4) the person suffering the death or the injury to his person or property was one of the class of persons for whose protection the statute, ordinance, or regulation was adopted.” *Quiroz v. Seventh Ave, Ctr*, 140 Cal.App. 4th 1256, 1285 (2006). In their Fourth Cause of Action, Plaintiffs assert that Defendants have violated 21

U.S.C. § 823(a) and implementing regulations, the purpose of which is to, among other things, maintain effective controls against diversion of controlled substances such as opioids, and protect the health and general welfare of the American people. NAS children are within the class of persons for whose protection the statute and regulations were adopted. Defendants' violations of these provisions have led to the injuries suffered by Legal Guardians and Putative Class Members. As with the elements of negligence, each element required for the negligence per se action presents a common issue of fact. *See, e.g., Lockheed Martin v. Carillo*, 29 Cal. 4th 1096, 1107 (2003).

3. The Violations of the Unfair Competition Law (Fifth Cause of Action)

In their Fifth Cause of Action, Plaintiffs assert violations of the California Unfair Competition Law (UCL), citing violations of the Consumer Legal Remedies Act (CLRA), which specifically provides for a class action. Cal.Civ.Code § 1781. In accordance with the UCL and CLRA, Plaintiffs are seeking injunctive relief, including restitution of all costs incurred as a result of caring for an NAS child, disgorgement of profits realized by Defendants and civil penalties. Federal courts in California have consistently certified class actions in matters under the UCL and CLRA. *See Krueger v. Wyeth*, 310 FRD 468 (S.D. Cal. 2015); 2011 WL 8971449, No. 03V2496 (S.D. Cal. March 30, 2011) (hormone replacement therapy); *Zakaria v. Gerber Products Co.*, 2016 WL 6662723 (C.D. Cal., March 23, 2016) (infant formula); *Johns v. Bayer Corp.*, 280 FRD 551 (S.D. Cal. 2012) (vitamins). In fact, the California legislature specifically endorses class actions for violations of the UCL. As the California Supreme Court wrote in *in re Tobacco II Cases*, 46 Cal. 4th 298, 313 (2009), class actions serve an important role in the enforcement of consumers' rights:

As we commented in *Kraus v. Trinity Management Services, Inc.* (2000) 23 Cal.4th 116, [126, additional citations omitted] 'consumer class actions and representative UCL actions serve important roles in the enforcement of consumers' rights. [They] make it economically feasible to sue when individual claims are too small to justify the expense of litigation, and thereby encourage attorneys to undertake private

enforcement actions. Through the UCL a plaintiff may obtain restitution and/or injunctive relief against unfair or unlawful practices in order to protect the public and restore to the parties in interest money or property taken by means of unfair competition. These actions supplement the efforts of law enforcement and regulatory agencies. This court has repeatedly recognized the importance of these private enforcement efforts.”

As with the decades-long campaign by the tobacco industry of deceptive advertising and misleading statements, Defendants’ deceptive advertising and misleading statements relating to opioids is appropriate for class treatment under the UCL.

4. Medical Monitoring

The California Supreme Court has made clear that medical monitoring costs “are a compensable item of damage in a negligence action where the proofs demonstrate, through reliable medical expert testimony that the need for future monitoring is a reasonably certain consequence of the plaintiffs’ toxic exposure and that the recommended monitoring is reasonable.” *Potter v. Firestone*, 863 P. 2d 965 (1993). As shown by the Guardians’ experts and discussed above, in order to safeguard the NAS children, Plaintiffs and each of the Putative Class Members must demand ongoing medical monitoring and surveillance of NAS children. In *Lockheed v. Martin*, 29 Cal. 4th 1096, 1105-06 (2003), the California Supreme Court acknowledged that “no per se or categorical bar exists to a court’s finding medical monitoring claims for class treatment, as long as any individual issues the claims present are manageable.”³³ Indeed, in 1998, a federal court certified a class seeking medical monitoring based on exposure to radiation. *O’Connor v. Boeing*, 184 FRD 311, 338-39 (C.D. Cal 1998). The court in *Boeing* found, as here, that the medical monitoring plan was certifiable as a class and membership therein could be established by

³³ The Court in *Lockheed* found that actual dosages and variations in individual responses would have to be litigated individually, precluding class certification. By contrast, all NAS children require the same medical monitoring protocol.

objective standards.³⁴ Indeed, the members of the class are readily identifiable from medical records and pharmacy records. The use of uniform billing codes and other objective diagnostic criteria that will be found in medical records for NAS-diagnosed children will render this determination a simple mechanical one. As such, any individual issues that the claims present here are manageable. As discussed, Plaintiffs meet all the criteria for class certification, and the Court should certify the class for the purposes of seeking medical monitoring.

XI. OTHER PARTIES ARE IGNORING THE INTERESTS OF THE GUARDIANS AND THE NAS CHILDREN

A. The PSC

The lawyers appointed to the PSC individually represent significant numbers of cities and counties. Consequently, and as the fiduciary duty requires, they have devoted themselves solely to the pursuit of the cities' and counties' interests and have ignored the conflicting interests of non-clients, including the Guardians and the NAS Children. These lawyers have done the same in the Purdue bankruptcy proceeding, where all claimants are competing for shares of a limited fund. They know that any funds given to the Guardians or the NAS Children will leave less money for the cities and counties, so they are fighting to secure for their clients the largest possible share.

When moving to certify a class of cities and counties, the PEC observed that “[s]ome method must be found to conserve finite funds otherwise exhausted in replicative litigation, ***and to allocate them fairly among all who need them.***”³⁵ Memorandum of Law, (Dkt. 1820-1) (emphasis added). It is abundantly clear that the Guardians and the NAS Children will be treated

³⁴ The Court in *Boeing* later decertified the class on grounds that the limitations defense made treatment inappropriate. See *O'Connor v. Boeing*, 197 FRD 404 (C.D. Cal. 2000). Here, by contrast, there is no issue relating to limitations due to both minor status and the ongoing care duty of the Guardians.

³⁵ Somehow, though, the PEC has come to believe that it is some extra-judicial arbiter of claims and fairness who can choose which of the claimants to help and which to abandon.

fairly only if they are represented by lawyers who are devoted solely to them. The need to allocate funds fairly makes the certification of a class of Guardians practically and ethically imperative.

B. Litigation, Settlement Negotiations, and Damage Awards Are Moving Forward Without Consideration for the NAS Children

The necessity of allowing the Guardians' class-wide claims to move forward without further delay is also especially critical where multiple claimants are competing for and even winning relief from Defendants in early bellwether proceedings, as well as working to establish the *gravitas* of their claims for the limited shares of bankrupt estate and within the MDL structure. Additionally, the Court "has repeatedly expressed a desire to settle the [opioid] litigation before it proceeds to trial." 2019 WL 4307851. The Guardians cannot allow the NAS Children to be left behind in this process. In order that the NAS Children's needs are properly weighed by Defendants and the varying claimants, the Guardians must insist that this Court recognize the class-wide merit of their claims so that they too have an opportunity to have their voices heard in current negotiations. And, of course, if the NAS Children's care needs are not properly addressed, Class Representatives and their counsel will proceed to trial. By certifying the Guardians' classes, the Court will enable them to negotiate with Defendants, prepare for trial, and protect the NAS Children's care needs against the encroachment of other claimants.

C. The Governmental Entities that Neither Represent the NAS Children *Parens Patriae* Nor Can Release Their Claims

Governmental entities, paradigmatically states, acting as *parens patriae* can "represent the interests of their citizens in enjoining public nuisances." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 603, 102 S. Ct. 3260, 3266, 73 L. Ed. 2d 995 (1982). To sue in *parens patriae*, however, a state "must articulate an interest apart from the interests of particular private parties," that is, a sovereign or quasi-sovereign interest. *Id.* at 607. Because the "[i]nterests of private parties are obviously not in themselves sovereign interests" of any type, *id.* at 602, the

governmental entities that belong to the existing negotiation class lack standing to assert them. Consequently, they can neither sue on behalf of the Guardians or the NAS Children nor release their private claims.

The Tenth Circuit reached exactly this conclusion in *Satsky v. Paramount Commc'ns, Inc.*, 7 F.3d 1464 (10th Cir. 1993). There, the question was whether a consent decree entered into by the State of Colorado prevented private individuals who subsequently asserted claims for personal injuries, property damage, and economic losses from suing. Even though the consent decree contained a broad release, the Tenth Circuit allowed the individuals to sue. The consent decree did not release the individuals' claims because "a state may not sue to assert the rights of private individuals." *Id.* at 1469 (citing *Snapp & Son*, 458 U.S. at 600; *Pennsylvania v. New Jersey*, 426 U.S. 660, 665 (1976); *New York by Abrams v. Seneci*, 817 F.2d 1015, 1017 (2nd Cir. 1987); *Illinois v. Life of Mid-America Ins. Co.*, 805 F.2d 763, 766 (7th Cir. 1986), and 13A Charles A. Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice & Procedure: Jurisdiction* 2d § 3531.11 at 19 (1984). Lacking power to assert private claims, Colorado could not release them either.

The Sixth Circuit has also recognized that a governmental entity lacks standing to assert a claim held by a private individual. In *Chapman v. Tristar Prod., Inc.*, 940 F.3d 299, 306 (6th Cir. 2019), it held that Arizona lacked standing to appeal the fairness of a class action settlement because "the only objections that Arizona can make are indistinguishable from the objections which individual Arizonans might raise." Having failed to assert an independent sovereign interest, Arizona could not sue. Similarly, the governmental entities herein do not have sovereign or semi-sovereign interests that are concomitant with those of the Guardians or the NAS Children and cannot assert or release claims the latter hold individually.³⁶

³⁶ The governmental entities are in a *parens patriae* relationship with NAS children who are wards of the

The clarity of the law notwithstanding, lawyers for some governmental entities have asserted that their clients and other members of the Negotiation Class are entitled to sue *parens patriae* because they are obligated “to keep them [the NAS Children] safe and healthy as they grow.” *Plaintiffs Statement of Interest in Response to Proposed Class Counsels’ Amended Joint Proposed Scheduling Order and Positions on Scheduling*, (Dkt. 27120). The lawyers identified no legal basis for this purported duty, however, and the Guardians know of none. Moreover, if such a duty does exist, the entities have been ignoring it since the start of the opioid crisis.

Addressing the legal limits of these governmental claims, this Court rightly recognized (though in a different context), that they are based upon a “clearly faulty premise.” *In re: State of Ohio Originating Case*, Case No. 19-3827 (6th Cir. 2019), Letter of this Court, dated October 1, 2019 (Dkt. 23). This Court explained the “faulty premise,” writing:

While it may be true that “**a political subdivision may not sue to enforce it residents’ rights**,” the bellwether Plaintiffs have consistently stated, and I have likewise repeatedly concluded, that **the city and county Plaintiffs do not seek to recover based on injuries to individual residents**; rather the Plaintiffs seek recovery for direct injuries suffered by the Plaintiffs themselves.

Id. (internal citations omitted and emphasis added).

Regardless, this Court went on to speculate that relief recovered by these governmental entities “will also tend to collaterally benefit their residents,” but that “this does not mean that Plaintiffs seek to litigate on behalf of those residents.” *Id.* While the NAS Guardians offer a cautious prayer that largesse from settlement-rich governmental entities might somehow trickle down to “collaterally” benefit the NAS Children (as this Court is hopeful), **the Guardians are the only entities who have a clear fiduciary duty to care for the NAS Children and a legal right**

States and can sue to recover the cost of caring for them. Those children are excluded from the class.

to sue on their behalf. This is why only the Guardians have sought relief that is tailored to the NAS Children's specific needs.

The Representatives of the Negotiation Class have already admitted to this Court that they cannot bind the class members to use prospective funds for any specific purpose, much less to pay for long-term and expensive medical monitoring and surveillance. Nothing in their Motion, Memorandum, FAQs, or other associated filings would require the governmental entities in the class to use any amount of funds to alleviate the financial burden that caring for the NAS Children imposes on the Guardians. Record, *passim*. Even if they are successful, city and county elected officials will receive unrestricted monies they can use however they please. They can balance their budgets, meet unfunded pension obligations, pave roads, promote tourism, or spend the money in other ways that local officials prefer.

It is time to put to rest the fiction that the cities and counties have the same legal duty to care for the NAS Children that the Guardians do.³⁷ The Court can do this by asking the government entities to swear on the record that they owe fiduciary duties to the NAS Children and by ordering them to make a fully-funded medical monitoring and treatment program for the Children part of their settlement negotiations.³⁸ Movants expect that few cities or counties, if any, will agree to these requirements. Only the Guardians stand willing, ready, and able to protect the NAS Children and to seek a settlement or judgment that advances their interests.

D. The Allocation Model for the Proposed Negotiation Class Ignores the Needs of the NAS Children and the Guardians

³⁷ The matter is, of course, on appeal in the Sixth Circuit.

³⁸ In the alternative, the Putative NAS Guardian Class Representatives should be granted leave to depose and propound written discovery on the Putative City and County Negotiation Class Representatives on these matters.

In the event that the PSC somehow might negotiate a global settlement for the cities and counties, the putative class representatives have set out a proposed settlement Allocation Model that assigns weight to (1) the volume of opioids distributed in a county, (2) the number of opioid deaths in a county, and (3) the number of persons suffering from “opioid use disorder” in the county. *Cities/Counties Negotiation Class Frequently Asked Questions (“FAQs”)*, (Dkt. 1820-2).

The factors contained in the Allocation Model are not proxies for the number of NAS Children and Guardians because (1) the volume of opioids “distributed” in a county is in no way a proxy for the number of NAS Children and Guardians living in that county; (2) unlike the tragic victims of fatal overdoses, the NAS Children and their Guardians are very much alive, and (3) “opioid use disorder” (OUD) is a clinical, diagnostic term which necessarily excludes the NAS Children. OUD is defined as the “signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose.” Diagnostic and Statistical Manual of Mental Disorders, 5th ed., American Psychiatric Assoc. (2013).

The fundamental problem with all of these self-selected factors is that opioid consumption and its consequences vary across demographic groups. For example, in 2017, more than twice as many men as women died from opioid abuse.³⁹ The “deaths per county” factor in the allocation formula will therefore strongly favor counties that skew male, to the disadvantage of NAS Children, all of whom were born to women. Historically, younger people, i.e., those whose ages range from 15 to 24 or from 25 to 34, have also died at lower rates than other opioid users.⁴⁰

³⁹ Attached as Dann Decl., Exhibit 9 is National Center for Health Statistics, Drug Overdose Deaths in the United States, 1999–2017, NCHS Data Brief No. 329 (2018), <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf>.

⁴⁰ *Id.*

Though OUD necessarily excludes children by its very definition (OUD is limited to adults who intentionally use opioids), the prevalence of OUD in adults also correlates poorly with the number of NAS Children. One reason is that OUD is more likely to be diagnosed in users who have health insurance than in uninsured users because the latter are less likely to visit physicians.⁴¹ Unless insurance coverage affects the birth rate for NAS Children similarly, the OUD factor will allocate funds without regard to the number of NAS Children, counties with large numbers of them will again be shortchanged, and NAS Children who live in these counties will again be neglected. And, because young men are far more likely to be diagnosed with OUD than young women, the gender skew will make matters even worse. *Id.*

Second, in addition to ignoring the NAS Children, the proposed allocation model is a public policy disaster which promotes ill-considered and inadequate governing, policing, and public health efforts. Perversely, the counties that did the least to combat the Defendants, to limit the flow of opiates, to prevent fatal overdoses, and help addicted adults are the most richly rewarded. Counties that have historically behaved responsibly in these areas by funding proactive anti-addiction measures and dedicating policing and social services resources will be severely under-compensated.⁴² Those governmental entities least capable of managing their affairs will be favored over the actual victims, such as the NAS Children and their Guardians, but also over other governmental entities that worked most effectively to combat the effects of Defendants' bad acts.

⁴¹ Attached as Dann Decl., Exhibit 11 is Stoddard Davenport and Katie Matthews, Opioid use disorder in the United States: Diagnosed prevalence by payer, age, sex, and state (2018), <http://www.milliman.com/insight/2018/Opioid-use-disorder-in-the-United-States-Diagnosed-prevalence-by-payer--age--sex--and-state>.

⁴² Obviously, these are laudable governmental functions. There are not, however, anywhere similar to the fiduciary care duties the NAS Guardians owe to the NAS Children.

E. The Proposed Cuyahoga County, Ohio Settlement Disposition Ignores the NAS Children

The plan that Cuyahoga County, Ohio announced in October of 2019 to distribute settlement funds garnered on the eve of its bellwether trial illustrates the reality that the needs of the Guardians and the NAS Children will be neglected by governmental entities. It proposes to use its funds as follows:

- 47% (\$10.9 M) for treatment and programming for current adult addicts suffering from Opioid Use Disorder (OUD);
- 32% (\$7.35 M) for Policing and Detention services;
- 20% (\$4.5M) for Foster Care services;⁴³ and
- 0.17% (\$400k) for “K-12 educational services.”⁴⁴

Not one penny of Cuyahoga County’s proposed settlement allocation will benefit the NAS Children aged 0-5 who are the focus of Plaintiffs’ proposed Ohio statewide Class. And, using current U.S. Census Bureau estimates,⁴⁵ we can further determine that Cuyahoga County’s *only* proposed “collateral benefit” to that county’s NAS Guardians and Children is a one-time and paltry \$2.15 per child aged 5-18 for undefined “educational training” for public school teachers. (It is unknown if this training is for addiction prevention, much less whether it is targeted for the educational needs of NAS Children.) Amortizing this over the life of a recently-born NAS Child, the “collateral benefit” Cuyahoga County it proposes to confer upon one of the neediest casualties

⁴³ \$1M is for boarding and care of foster care children who are already in state care and is in no way specifically targeted towards NAS children or even children who are in placement due to the opioid crisis. This line item appears to be a simple budget-balancing technique for pre-existing obligations. The other \$3.5M is to hire new staff members for the department that manages foster care. *Id.*

⁴⁴ Attached as Dann Decl., Exhibit 12 is “Cuyahoga County Announces How It’ll Use \$23 Million in Opioid Settlement Money on Treatment and Prevention Services,” Vince Grzegorek, October 11, 2019, clevescene.com.

⁴⁵ Fifteen percent of Cuyahoga County’s population is aged 5-18. <https://www.census.gov/quickfacts/fact/table/cuyahogacountyohio,US/PST045218>.

of the opioid crisis plummets to *less than 12 cents a year*. **If there is something less than *de minimis* or smaller than a peppercorn, this is it.**

F. The State of Oklahoma Made No Claims Relating to an Ongoing Duty of Care for the NAS Children

As the Court is aware, a lengthy bench trial occurred in Oklahoma State Court in 2019, resulting in a judgment against many of the Opiate Defendants and in favor of the State of Oklahoma's public nuisance claims. Based on the State's proof, the trial court made certain findings regarding NAS Children in Oklahoma. However, it must be appreciated that Oklahoma made absolutely no claims, nor put on any proof regarding care for the NAS Children **after their birth**. *State of Oklahoma v. Purdue Pharma L.P.*, Case No. CJ-2017-816 (Cleveland County Dist. Ct., Okla.) (August 29, 2019), Judgment at p. 35-37, ¶¶ 25-35) ("Abatement of the Nuisance"). While the objectives of Oklahoma's efforts are laudable and welcomed, they have no applicability to the ongoing care duties of the Guardians, nor do they benefit the NAS Children after their hospital discharge. *Id.*, *passim*.

G. The Known Risk of Governmental "Slush Funds"

As this Court is aware, the risk of enabling vast governmental "slush funds" that never result in trickle-down benefits for victims is very real. Attempts to create "lock boxes" to protect opioid litigation recoveries from state legislatures (such as that proposed by the Ohio Attorney General⁴⁶) are laudable, but highlight the inherent flaws in these settlements and judgments, as well as the fact that "lock boxes" are often quite unpopular with elected officials. A state government cannot be told by this MDL Court how to spend its money, nor is any state, county,

⁴⁶ Ohio Attorney General Dave Yost's proposal is opposed by Ohio Gov. Mike DeWine and has not been championed, nor, apparently, even discussed by the Ohio State Legislature. Attached as Dann Decl., Exhibit 13 is Darrel Rowland and Randy Ludow, "Ohio voters could decide constitutional amendment to split up opioid lawsuit cash," *The Columbus Dispatch*, December 5, 2019.

or city pledging to restrict funds nor otherwise bind itself ahead of litigation or settlement negotiations with the Opioid Defendants to dispose of a potential recovery in any specific manner.⁴⁷

As this Court is aware, governmental entities are not strongly inclined to help vulnerable persons and cannot be obligated by courts to do so. A study of the uses six states made of funds paid out by the tobacco settlement summarized its findings as follows:

State allocation decisions were diverse; substantial shares were allocated to areas other than tobacco control and health, including capital projects and budget shortfalls. The allocations did not reflect the stated goals of the lawsuits leading to the settlements. This outcome reflects a lack of strong advocacy from public health interest groups, an unreliable public constituency for tobacco control, and inconsistent support from state executive and legislative branches, all combined with sizable budget deficits that provided competing uses for settlement funds.

Frank A. Sloan, Jennifer S. Allsbrook, Leanne K. Madre, Leah E. Masselink, and Carrie A. Mathews, “States’ Allocations Of Funds From The Tobacco Master Settlement Agreement,” *Health Affairs*, Vol. 24 (2005). The cities and counties that are involved in this MDL are no more trustworthy than the states. They cannot be relied upon to use the funds they receive to provide the NAS Children the help they need, especially where they have no duty to do so. It is also self-evident that children are not voters, and programs that benefit those who do not vote are the most vulnerable to legislative vicissitudes.

XII. CONCLUSION

For the reasons stated herein, Movants ask the Court to certify two nationwide RICO classes of Guardians of NAS Children (one where the birth mother’s opioids prescription came at

⁴⁷ The only mention of the “use” of settlement proceeds is a non-binding recommendation from the PEC that it would “prefer” that “each State … reach agreement with the cities and counties with the State on the allocation and use of the [settlement] money within the State.” (Dkt. 1820-2).

any point prior to the birth of and NAS Child and one where the prescription came during pregnancy), as well as statewide class actions for California and Ohio.

DATED: January 7, 2020

Respectfully submitted,

/s/ Marc E. Dann
DANN LAW
Marc E. Dann (0039425)
P.O. Box 6031040
Cleveland, OH 44103
Telephone: 216-373-0539
Facsimile: 216-373-0536
notices@dannlaw.com
Counsel for NAS Plaintiffs

/s/ Celeste Brustowicz
COOPER LAW FIRM, LLC
Celeste Brustowicz (*Pro Hac Vice*)
Barry J. Cooper, Jr. (*Pro Hac Vice*)
Stephen H. Wussow (*Pro Hac Vice*)
Victor Cobb (*Pro Hac Vice*)
1525 Religious St.
New Orleans, LA 70130
Telephone: 504-399-0009
cbrustowicz@sch-llc.com
Counsel for NAS Plaintiffs

/s/ Kent Harrison Robbins
THE LAW OFFICES OF
KENT HARRISON ROBBINS, P.A.
Kent Harrison Robbins (*Pro Hac Vice*)
242 N.E. 27th St.
Miami, FL 33137
Telephone: 305-532-0500
Facsimile: 305-531-0150
khr@khrlawoffices.com
Counsel for NAS Plaintiffs

/s/ Scott R. Bickford
MARTZELL, BICKFORD & CENTOLA
Scott R. Bickford (La. 1165)
Spencer R. Doody (La. 27795)
338 Lafayette St.
New Orleans, LA 70130
Telephone: 504-581-9065
srb@mbfirm.com
Counsel for NAS Plaintiffs

/s/ Kevin W. Thompson
THOMPSON BARNEY LAW FIRM
Kevin W. Thompson (*Pro Hac Vice*)
David R. Barney, Jr. (*Pro Hac Vice*)
2030 Kanawha Blvd.
East Charleston, WV 25311
Telephone: 304-343-4401
Facsimile: 304-343-4405
kwthompsonwv@gmail.com
Counsel for NAS Plaintiffs

/s/ Donald Creadore
THE CREADORE LAW FIRM, P.C.
Donald Creadore (NY Reg. No. 2090702)
450 7th Ave. – 1408
New York, NY 10123
Telephone: 212-355-7200
Facsimile: 212-583-0412
donald@creadorelawfirm.com
Counsel for NAS Plaintiffs